

Exhibit B

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Thomas R. Brezina, CRR, RMR, CCR-B-2035

Joye Lowman, M.D.

<div>Page 2</div> <div>1 APPEARANCES OF COUNSEL: 2 On behalf of the Plaintiffs Bailey and Bishop: 3 FRED THOMPSON, III, ESQUIRE 4 Motley Rice LLC 5 28 Bridgeside Boulevard 6 Mount Pleasant, South Carolina 29464 7 (843) 216-9000 8 fthompson@motleyrice.com 9 10 PAIGE BOLDT, ESQUIRE 11 (present via speakerphone) 12 Watts Guerra, LLP 13 4 Dominion Drive 14 Building 3, Suite 100 15 San Antonio, Texas 78257 16 (210) 447-0500 17 pboldt@wattsguerra.com 18 19 On behalf of the Defendants: 20 ERIC RUMANEK, ESQUIRE 21 SHAWN N. SKOLKY, ESQUIRE 22 Troutman Sanders LLP 23 Bank of America Plaza 24 600 Peachtree Street, NE Suite 5200 Atlanta, Georgia 30308 (404) 885-3000 eric.rumanek@troutmansanders.com shawn.skolky@troutmansanders.com - - -</div>	<div>Page 4</div> <div>1 INDEX OF EXHIBITS 2 Plaintiffs' Description Page 3 Exhibit P-8 Clinical Expert Report 73 4 Bates stamped 5 ETH.MESH.000167104 through 6 ETH.MESH.000167110 and 7 photocopies of slides 8 dtd April 18, 2006 9 10 Exhibit P-9 TVT IFU Bates stamped 78 11 ETH.MESH.02340306 12 through ETH.MESH.02340369 13 14 Exhibit P-10 Document entitled, 87 15 "Gynecare TVT Obturator 16 System" 17 Exhibit P-11 One-page spreadsheet 95 18 entitled, "Dr. Lowman 19 case hours" 20 Exhibit P-12 AUGS Position Statement 100 21 on Mesh Midurethral 22 Slings for Stress 23 Urinary Incontinence 24 25 Exhibit P-13 Three pages of 112 26 handwritten notes of 27 Dr. Lowman</div>
<div>Page 3</div> <div>1 INDEX OF EXAMINATIONS 2 Page 3 Examination by Mr. Thompson 5 4 Examination by Mr. Rumanek 110 5 Further Examination by Mr. Thompson 112 6 7 INDEX OF EXHIBITS 8 Plaintiffs' Description Page 9 Exhibit P-1 Notice to Take Deposition 5 10 of Joye K. Lowman, MD 11 dtd June 22, 2016 12 Exhibit P-2 Case Specific Expert 8 13 Report of Joye K. Lowman, 14 MD, MPH 15 Exhibit P-3 Curriculum Vitae of 8 16 Joye K. Lowman, MD, MPH 17 18 Exhibit P-4 Reliance List in Addition 8 19 to Materials Referenced 20 in Report Pamela Bailey 21 22 Exhibit P-5 Supplemental Reliance List 9 23 in Addition to Materials 24 Referenced in Report Pamela Bailey Exhibit P-6 Printout from AUGS website 10 entitled, "Organizations Lend their Support to Mid-urethral Slings" Exhibit P-7 AUGS Position Statement 10 on Mesh Midurethral Slings for Stress Urinary Incontinence</div>	<div>Page 5</div> <div>1 JOYE LOWMAN, MD., 2 having been produced and first duly sworn as a 3 witness, testified as follows: 4 EXAMINATION 5 BY MR. THOMPSON: 6 Q Doctor, my name is Fred Thompson. Before 7 we start asking questions I would need to make a 8 couple of statements on the record. Our subpoena 9 duces tecum, actually as do most of these, has a 10 lengthy list of items asking you to bring them to the 11 deposition. Let me go ahead and make this as 12 Deposition Exhibit Number 1. 13 (Plaintiffs' Exhibit Number P-1 was 14 marked for identification.) 15 BY MR. THOMPSON: 16 Q And let me just hand that to you really 17 quickly. 18 A Uh-huh. 19 Q Now, Doctor, do the -- apparently the 20 times and the parties are not exactly correct as we 21 get further down the page, but this morning we're 22 going to be taking a deposition with regard to some 23 general opinions that you have expressed in your 24 report, and then we're going to take a deposition with</div>

<p style="text-align: right;">Page 6</p> <p>1 regard to Miss Bailey, and both of those are time 2 limited.</p> <p>3 As part of that deposition we had an 4 attachment where we asked you bring certain documents 5 with you, certain documents that you relied upon or 6 that were provided to you or that you found as a 7 result of your investigation, and I see -- and I've 8 had an opportunity to look at, I believe it's seven or 9 eight Bankers Boxes of documents that were brought to 10 the deposition room with you. Are those the documents 11 -- oh, and in addition I've been provided with two 12 thumb drives of documents which are responsive to this 13 request as well.</p> <p>14 Are there any other documents that you 15 have in your possession or within your control that 16 have not been provided here today?</p> <p>17 MR. RUMANEK: And let me just interject 18 really quickly before she answers the question. 19 So just for the record, Plaintiffs' Exhibit 1 20 is a deposition notice that was filed on 21 June 22, which was just two days ago, and we 22 have not filed objections to that notice of 23 deposition yet, but we will be objecting, and 24 under the rules we have ten days to do so, so</p>	<p style="text-align: right;">Page 8</p> <p>1 want to say on the record just so that it's 2 clear, some of the boxes and some of the 3 binders of material within the boxes are not 4 specific to her TVT opinions or the Bailey 5 case. I think she brought everything that she 6 had that would be relevant and responsive to 7 all of the depositions that she is giving over 8 the next couple of days, so just so that is 9 clear.</p> <p>10 MR. THOMPSON: All right.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q Let me turn to the report, the reliance 13 list, and the CV.</p> <p>14 MR. THOMPSON: If we could mark these as 15 two, three, and four. 16 (Plaintiffs' Exhibits Numbers P-2, P-3, 17 and P-4 were marked for identification.)</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q Dr. Lowman, I'm going to hand you two, 20 three, and four, which I believe are copies of the 21 report, the CV, and the reliance materials that you 22 served in the Bailey case.</p> <p>23 A Okay.</p> <p>24 MR. RUMANEK: Fred, let me --</p>
<p style="text-align: right;">Page 7</p> <p>1 with that, I think you can answer the question.</p> <p>2 THE WITNESS: So in addition to the 3 recent update to the position statement on 4 mid-urethral slings that was brought today, I 5 have everything that I considered in 6 formulating this report.</p> <p>7 BY MR. THOMPSON:</p> <p>8 Q Now, we have identified a couple of 9 binders that I believe that I'm going to make 10 reference to during the deposition, but in the sense 11 of keeping the court reporter from lugging eight boxes 12 out of here, what I would like to have with the 13 defendant is an agreement that either you or the 14 defendants' attorney can remain in possession of these 15 documents and that they will not be destroyed and will 16 be available in the future if proper notice and proper 17 need is shown to review them.</p> <p>18 MR. THOMPSON: Is that an agreement that 19 we can have?</p> <p>20 MR. RUMANEK: Yeah. I think that's fine, 21 and we'll respond accordingly at the 22 appropriate time if such a request is made.</p> <p>23 MR. THOMPSON: All right.</p> <p>24 MR. RUMANEK: And the only other thing I</p>	<p style="text-align: right;">Page 9</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q I noticed that you brought with you -- 3 I'm sorry.</p> <p>4 MR. RUMANEK: No. I just wanted to note 5 that I believe there has been a supplemental 6 reliance list that's been served. I've not 7 compared what's on the reliance list to the 8 supplemental one, but I do have a copy of the 9 supplemental one if you want to mark that --</p> <p>10 MR. THOMPSON: Yeah, please.</p> <p>11 MR. RUMANEK: -- just for completion 12 sake.</p> <p>13 MR. THOMPSON: Okay. I'd note for the 14 record that it's twice as big as the original 15 one.</p> <p>16 MR. RUMANEK: I don't know if it's double 17 sided or --</p> <p>18 MR. THOMPSON: How about make this the 19 next one. 20 (Plaintiffs' Exhibit Number P-5 was 21 marked for identification.)</p> <p>22 BY MR. THOMPSON:</p> <p>23 Q And I will hand you this supplemental.</p> <p>24 MR. THOMPSON: And then let's just go</p>

<p style="text-align: right;">Page 10</p> <p>1 ahead so that we have everything in one place</p> <p>2 at one time -- I believe last night and this</p> <p>3 morning the supplemental list was supplemented</p> <p>4 with an additional statement from, it looks</p> <p>5 like a letter from the AUGS president and a</p> <p>6 position statement of AUGS, so let's mark those</p> <p>7 as the next two exhibits.</p> <p>8 MR. RUMANEK: And I will just say on the</p> <p>9 record, I don't know if your characterization</p> <p>10 is correct about a supplemental reliance list</p> <p>11 adding those two. To the extent that there was</p> <p>12 a supplemental reliance list that was served by</p> <p>13 Butler Snow yesterday evening, I can't confirm</p> <p>14 or deny whether it added only those two</p> <p>15 documents.</p> <p>16 (Plaintiffs' Exhibits Numbers P-6 and P-7</p> <p>17 were marked for identification.)</p> <p>18 MR. RUMANEK: I didn't see a supplemental</p> <p>19 reliance list that was served as to Dr. Lowman.</p> <p>20 MR. THOMPSON: The supplemental was the</p> <p>21 giant list that you just sent me, so --</p> <p>22 BY MR. THOMPSON:</p> <p>23 Q Well, let me go ahead and hand you</p> <p>24 Plaintiffs' Exhibit 6 and 7 as well.</p>	<p style="text-align: right;">Page 12</p> <p>1 (Discussion ensued off the record.)</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q Let's go straight to -- Doctor, what is</p> <p>4 your specialty?</p> <p>5 A Female pelvic medicine and reconstructive</p> <p>6 surgery.</p> <p>7 Q And you have an MD degree; is that</p> <p>8 correct?</p> <p>9 A MD and a master's in public health as</p> <p>10 well.</p> <p>11 Q Doctor, I note that you work at Kaiser</p> <p>12 Permanente; is that correct?</p> <p>13 A That's correct.</p> <p>14 Q And that is a -- back in the old days we</p> <p>15 would call that an HMO, but what is that? What is</p> <p>16 Kaiser Permanente?</p> <p>17 A I think that's an accurate</p> <p>18 characterization: Health management organization.</p> <p>19 Q I'm very familiar with Kaiser in</p> <p>20 California.</p> <p>21 A Uh-huh.</p> <p>22 Q I'm not so familiar with Kaiser in other</p> <p>23 states. What is your enrollment in Georgia?</p> <p>24 A Approximately 250,000 members when I</p>
<p style="text-align: right;">Page 11</p> <p>1 A Okay.</p> <p>2 Q And, Doctor, these are two documents that</p> <p>3 your counsel brought with you to the room this morning</p> <p>4 and said that those were additional reliance materials</p> <p>5 that you incorporate into your views and opinions in</p> <p>6 this case. Is that correct?</p> <p>7 A That's correct.</p> <p>8 Q Since those are the only copies I have,</p> <p>9 let's put them back in the middle of the page. Now,</p> <p>10 with regard to the report, I note that you brought a</p> <p>11 copy of the report with you.</p> <p>12 A Uh-huh.</p> <p>13 Q And if, in fact, you have -- if you're</p> <p>14 comfortable using yours, feel free to do that. I've</p> <p>15 simply marked these so that the record will have an</p> <p>16 exhibit that people six months, a year, two years,</p> <p>17 heaven knows, will have a reference so that they can</p> <p>18 have a copy of the exhibit when they review the</p> <p>19 transcript, but feel free to use your copy if you are</p> <p>20 more comfortable with that. Okay?</p> <p>21 A All right.</p> <p>22 MR. RUMANEK: Fred, can we go off the</p> <p>23 record just a second?</p> <p>24 MR. THOMPSON: Yeah.</p>	<p style="text-align: right;">Page 13</p> <p>1 started. That number has gone a little bit up and</p> <p>2 then a little bit down and then a lot up over the past</p> <p>3 year and a half or so, so I would have to guesstimate</p> <p>4 maybe 260,000 or so.</p> <p>5 Q Now, tell me your position within Kaiser.</p> <p>6 A I started the urogynecology department,</p> <p>7 so I'm the lead of the urogynecology department.</p> <p>8 Q And is that for the entire patient</p> <p>9 population?</p> <p>10 A It is.</p> <p>11 Q And do you have -- if there is a</p> <p>12 hierarchy, are you the person in charge of OB-GYNs</p> <p>13 that are -- or gynecologists that perform services for</p> <p>14 Kaiser Permanente patients?</p> <p>15 A I am not in charge of women's services,</p> <p>16 so I'm not the chief of the OB-GYN department, but I'm</p> <p>17 the lead of the urogynecology services.</p> <p>18 Q I see. Now, does that include you making</p> <p>19 policy and you making decisions that are reflected in</p> <p>20 protocols and directives that have to be followed?</p> <p>21 MR. RUMANEK: Objection to form.</p> <p>22 THE WITNESS: Somewhat. That has to be</p> <p>23 done in consultation with the chief of women's</p> <p>24 services, with our risk management department,</p>

<p style="text-align: right;">Page 14</p> <p>1 and with a whole host of administrators.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q Now, do those instructions or protocols</p> <p>4 or -- maybe I'm being too authoritarian, but the way</p> <p>5 in which you manage the people who are within your</p> <p>6 department, are those kept in sort of a permanent</p> <p>7 source material that's referred to? If somebody has a</p> <p>8 question, that they can go and look it up?</p> <p>9 MR. RUMANEK: Objection to form.</p> <p>10 THE WITNESS: Do we have protocols?</p> <p>11 You're talking about clinical practice</p> <p>12 guidelines?</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q Yes, ma'am.</p> <p>15 A We don't in general. Well, let me think</p> <p>16 about that. I don't believe that we actually have</p> <p>17 clinical practice guidelines that are issued by</p> <p>18 Kaiser. Now, we have sort of monthly department</p> <p>19 meetings where we discuss issues that might be coming</p> <p>20 up within the department, and the chief will sort of</p> <p>21 suggest changes to sort of the -- what they call work</p> <p>22 flows, the way we sort of usually do things commonly</p> <p>23 in the department.</p> <p>24 But in general we base our practice on</p>	<p style="text-align: right;">Page 16</p> <p>1 academic practice.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q I see.</p> <p>4 A In fellowship it was academic, sort of,</p> <p>5 but it was a private practice sort of situated within</p> <p>6 a university setting, and now Kaiser is very different</p> <p>7 because it's not considered an academic institution.</p> <p>8 Q Yes.</p> <p>9 A It's, you know, an HMO, so all of those</p> <p>10 practice settings have actually been quite different.</p> <p>11 Q I see. But since 2008 --</p> <p>12 A Yes.</p> <p>13 Q -- since you left your fellowship, Kaiser</p> <p>14 has been your employer?</p> <p>15 MR. RUMANEK: Let me just remind for the</p> <p>16 record, and I don't mean to interrupt your</p> <p>17 question, but you may anticipate what he's</p> <p>18 going to say, but make sure you let him finish</p> <p>19 the question before you start your answer just</p> <p>20 so you're not talking -- I've noticed that a</p> <p>21 couple of times. Just a reminder.</p> <p>22 THE WITNESS: Okay.</p> <p>23 BY MR. THOMPSON:</p> <p>24 Q Now, you may have noticed that that</p>
<p style="text-align: right;">Page 15</p> <p>1 guidelines that are issued by the American College and</p> <p>2 the American Urogynecologic Society and that kind of</p> <p>3 thing, so Kaiser does not usually issue practice</p> <p>4 guidelines, per se, for the department.</p> <p>5 Q I see. Okay. Doctor, I think you went</p> <p>6 to work for Kaiser in, is it 2007?</p> <p>7 A 2008.</p> <p>8 Q And you finished your residency in 2008?</p> <p>9 A 2005. I did a fellowship between 2005</p> <p>10 and 2008.</p> <p>11 Q Well, okay. The fellowship at Indiana?</p> <p>12 A Indiana University.</p> <p>13 Q And then you left Indiana and you came</p> <p>14 to?</p> <p>15 A Kaiser.</p> <p>16 Q To Kaiser?</p> <p>17 A Uh-huh.</p> <p>18 Q So this is the only way you've ever</p> <p>19 practiced medicine; is that correct?</p> <p>20 MR. RUMANEK: Objection to form.</p> <p>21 THE WITNESS: No. I've practiced</p> <p>22 medicine in -- differently in residency. I've</p> <p>23 practiced medicine differently in fellowship.</p> <p>24 In residency we were in a community-based</p>	<p style="text-align: right;">Page 17</p> <p>1 doesn't bother me at all.</p> <p>2 MR. RUMANEK: I'm trying --</p> <p>3 BY MR. THOMPSON:</p> <p>4 Q -- because I just love to have a chat</p> <p>5 with you, but your lawyer is correctly telling you</p> <p>6 that I'm not on your side. Okay? All right.</p> <p>7 MR. RUMANEK: I don't know that she</p> <p>8 answered your question, so I think I</p> <p>9 interrupted you, so I apologize for that.</p> <p>10 BY MR. THOMPSON:</p> <p>11 Q Well, the question is, since you left</p> <p>12 your fellowship in 2008, you've been continuously</p> <p>13 employed by Kaiser?</p> <p>14 A That's correct.</p> <p>15 Q Like I say, I'm familiar with Kaiser in</p> <p>16 California, and they have a giant patient population.</p> <p>17 I think it's between one and 2 million patients, and</p> <p>18 Kaiser may well be the best recordkeeper of -- private</p> <p>19 recordkeeper of patient histories, patient treatments,</p> <p>20 patient modalities of any organization in the country.</p> <p>21 Here's my question. That's a preface.</p> <p>22 The question is, does Kaiser keep a</p> <p>23 database on its 250,000 patients in Georgia?</p> <p>24 A No, not exactly. We do have electronic</p>

<p style="text-align: right;">Page 18</p> <p>1 medical records.</p> <p>2 Q Yes.</p> <p>3 A So we have data that could be made into a</p> <p>4 database, if you will. I mean, we have --</p> <p>5 Q Yeah.</p> <p>6 A -- you know, an electronic medical record</p> <p>7 that can be referenced, but we don't have databases,</p> <p>8 no.</p> <p>9 Q I guess my question is, for example,</p> <p>10 since -- let's just talk about the one I'm interested</p> <p>11 in. If you wanted to, you could go and find every</p> <p>12 single person that's had a Prolift device inserted in</p> <p>13 them, and if they're still enrolled, you could find</p> <p>14 out what's going on with them?</p> <p>15 MR. RUMANEK: Objection to form.</p> <p>16 BY MR. THOMPSON:</p> <p>17 Q Isn't that right?</p> <p>18 A No. Actually, I can't do that just</p> <p>19 because I want to do that. I have to actually request</p> <p>20 IRB approval, and they -- Kaiser's IRB department,</p> <p>21 their institutional review board, has to approve to</p> <p>22 allow me to conduct that human subjects research, and</p> <p>23 I've actually tried.</p> <p>24 Q Well, yeah. I'm not talking about doing</p>	<p style="text-align: right;">Page 20</p> <p>1 MR. RUMANEK: Objection to form.</p> <p>2 THE WITNESS: Not to my knowledge.</p> <p>3 BY MR. THOMPSON:</p> <p>4 Q Is there a formulary that has approved</p> <p>5 devices for your employees to use?</p> <p>6 A Not to my knowledge.</p> <p>7 Q Is there any reason why Kaiser would not</p> <p>8 use its market power to try to get a better deal from</p> <p>9 these companies?</p> <p>10 MR. RUMANEK: Objection to form to the</p> <p>11 extent you're asking her to testify as to what</p> <p>12 Kaiser --</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q Well, I'm assuming that you are a high --</p> <p>15 that you are like a muckety-muck, that you are high</p> <p>16 up, and if that's just above your pay grade, just tell</p> <p>17 me, and then we'll move on to something else, but why</p> <p>18 would they not have a formulary and negotiate better</p> <p>19 deals?</p> <p>20 MR. RUMANEK: Objection to form and the</p> <p>21 characterization.</p> <p>22 THE WITNESS: Well, it is above my pay</p> <p>23 grade, actually. I mean, that's an</p> <p>24 administrative issue. In general Kaiser</p>
<p style="text-align: right;">Page 19</p> <p>1 clinical trials. I'm simply talking about mining the</p> <p>2 data --</p> <p>3 A That's considered --</p> <p>4 Q -- that you already have.</p> <p>5 A That's --</p> <p>6 Q That's sensitive data under, like, HIPAA</p> <p>7 and stuff?</p> <p>8 A Absolutely.</p> <p>9 Q Now, why would they decline to let you do</p> <p>10 that if you said, I'm going to protect their</p> <p>11 confidentiality and I'm going to assign a random</p> <p>12 number for each patient and I'm going to address all</p> <p>13 of these problems? Why would they not -- why did they</p> <p>14 not approve your request?</p> <p>15 MR. RUMANEK: Objection to form.</p> <p>16 THE WITNESS: I don't know the answer to</p> <p>17 that. My suspicion is that they don't want to</p> <p>18 risk liability.</p> <p>19 BY MR. THOMPSON:</p> <p>20 Q I see. Okay. The next question I have</p> <p>21 is, does Kaiser conduct group purchases from medical</p> <p>22 device companies? Do they negotiate prices and</p> <p>23 products with medical device companies on behalf of</p> <p>24 the HMO?</p>	<p style="text-align: right;">Page 21</p> <p>1 doesn't like to align themselves with companies</p> <p>2 and sort of appear to possibly have conflicts</p> <p>3 of interest, and so they don't -- other than --</p> <p>4 they -- they obviously negotiate for</p> <p>5 pharmaceutical costs and things like that, but</p> <p>6 in terms of aligning themselves with certain</p> <p>7 devices, that would not be within their sort of</p> <p>8 philosophy.</p> <p>9 BY MR. THOMPSON:</p> <p>10 Q Is there any committee or any person</p> <p>11 within Kaiser that conducts comparative research? For</p> <p>12 example, head-to-head between the Advantage Fit versus</p> <p>13 a TVT or, you know, a Pinnacle versus a Prolift? Is</p> <p>14 there any organization within Kaiser that looks into</p> <p>15 that and makes those kinds of judgments on behalf of</p> <p>16 patients?</p> <p>17 A No.</p> <p>18 Q Is it left to the individual treating</p> <p>19 physician at Kaiser to determine which medical device</p> <p>20 he or she might select to implant in a patient?</p> <p>21 A Yes.</p> <p>22 Q When, for example, in April of 2012 the</p> <p>23 FDA required 522 studies for various pelvic floor</p> <p>24 products and the response from most companies was to</p>

<p style="text-align: right;">Page 22</p> <p>1 withdraw those products from the market -- you're 2 familiar with that; right? 3 MR. RUMANEK: Objection to form. 4 THE WITNESS: The vaginal mesh products, 5 yes. 6 BY MR. THOMPSON: 7 Q Was there any organized internal response 8 at Kaiser? Were there any committee meetings or any 9 discussions as to what should be done for or on behalf 10 of patients as a result of those withdrawals of those 11 pelvic floor products? 12 MR. RUMANEK: Fred, can I have just a 13 continuing objection to you asking her about 14 what went on within Kaiser? It may be beyond 15 what she knows. You're saying, were there any 16 meetings at Kaiser? 17 MR. THOMPSON: Well, okay. Well, let me 18 be instructed by that. 19 BY MR. THOMPSON: 20 Q Were you either in attendance or were 21 aware of any meetings where a firm-wide response or a 22 uniform firm response was considered as a result of 23 the withdrawal of those pelvic floor products? 24 A No. Not in response to withdrawal of</p>	<p style="text-align: right;">Page 24</p> <p>1 BY MR. THOMPSON: 2 Q I see. 3 A -- than obturator slings. 4 Q And was there a date that you can point 5 to that that was the date that you felt that the 6 evidence that you have just recited was sufficient for 7 you to not use TVT-O anymore? 8 MR. RUMANEK: Objection to form. 9 THE WITNESS: No. 10 BY MR. THOMPSON: 11 Q That was just over -- if I went to 2010, 12 were you still using both? 13 A No. 14 Q If I went to 2008? 15 A No. 16 Q I see. So while you were either in 17 residency or fellowship, you made that determination? 18 A That's correct. 19 Q And are you -- like I say, you described 20 your position as an -- and in my mind I have sort of a 21 supervisory thought process, but I guess the question 22 is, your personal decision that the TVT is superior to 23 the TVT-O, is that transmitted to other physicians who 24 may be within your department? I mean, is this a --</p>
<p style="text-align: right;">Page 23</p> <p>1 those products, no. 2 Q Was there any organized discussion as to 3 what the appropriate or what would be the best 4 alternative means of treatment for patients as a 5 result of those withdrawals? 6 MR. RUMANEK: Objection to form. 7 THE WITNESS: No. 8 BY MR. THOMPSON: 9 Q Doctor, in your report you indicated that 10 you have placed approximately 800 TVT and TVT-O 11 devices. Is that correct? I'm at page 2. 12 A Yes. 13 Q And do you use both TVT and TVT-O? 14 A No. 15 Q What do you use -- 16 A The TVT. 17 Q -- currently? Did you ever use TVT-O? 18 A I have used it before, yes. 19 Q And is there a reason why you exclusively 20 use TVT today? 21 MR. RUMANEK: Objection to form. 22 THE WITNESS: Yes. The retropubic route 23 has a lower risk of pelvic pain and groin pain 24 and has a higher success rate --</p>	<p style="text-align: right;">Page 25</p> <p>1 strike that. I'm asking a compound question. 2 Was your decision given any 3 organizational imprimatur? 4 A No. 5 Q So that remains a personal decision of 6 the doctors within your organization? 7 A That's correct. 8 Q How does Kaiser make sure that the 9 doctors who are doing mesh surgery are competent to do 10 it? 11 MR. RUMANEK: Objection to form, again to 12 the extent that you are asking her to testify 13 about Kaiser generally. 14 THE WITNESS: The only organizational 15 sort of check and balance, if you will, I would 16 say, is the peer review committee. 17 BY MR. THOMPSON: 18 Q I see. 19 A So hospitals in general credential 20 physicians to be able to perform procedures where they 21 have privileges. 22 Q Yes. 23 A Kaiser doesn't. That's not their job, 24 per se. But we do have a peer review committee that I</p>

<p style="text-align: right;">Page 26</p> <p>1 currently serve on that reviews sort of maloccurrences</p> <p>2 and outcomes that might be considered outside the</p> <p>3 standard of care to see whether or not someone is --</p> <p>4 is -- may need some, you know, additional support or</p> <p>5 if we need -- if we have a systems issue that might be</p> <p>6 -- that need to be addressed, something like that.</p> <p>7 Q I see. Now, and I don't want to get</p> <p>8 ahead of myself, but you criticized Dr. Perlow because</p> <p>9 he was having a ten to 20 percent, I believe,</p> <p>10 complication rate.</p> <p>11 MR. RUMANEK: Objection to form of the</p> <p>12 question.</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q Is that right?</p> <p>15 A I didn't criticize him, per se. I said</p> <p>16 his -- his rate of voiding dysfunction was higher than</p> <p>17 what is typically seen with mid-urethral slings.</p> <p>18 Q Now, if I flip on forward in your report,</p> <p>19 if I get to -- where am I? There we go. If I get to</p> <p>20 page 10 of your report --</p> <p>21 A Uh-huh.</p> <p>22 Q -- you state, "I have not had a single</p> <p>23 patient report dyspareunia, pelvic pain, or mesh</p> <p>24 erosion with a TVT in over 800 cases."</p>	<p style="text-align: right;">Page 28</p> <p>1 complication, yes.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q Are you familiar with the literature</p> <p>4 where the first 50 mesh cases has a much higher</p> <p>5 incidence of complication per -- if the surgeon begins</p> <p>6 using mesh, that his first 50 cases have a much higher</p> <p>7 percentage of complication?</p> <p>8 MR. RUMANEK: Objection to the form of</p> <p>9 the question to the extent that you are</p> <p>10 referencing medical literature and not showing</p> <p>11 it to the witness.</p> <p>12 THE WITNESS: I'm not familiar with the</p> <p>13 medical literature that you're referencing, but</p> <p>14 I would -- I would agree that that's probably</p> <p>15 the case, yes.</p> <p>16 BY MR. THOMPSON:</p> <p>17 Q Now, the difference in technique is known</p> <p>18 to -- let me strike that. Okay. Now, you recite in</p> <p>19 your report at page -- where are we here? At page 10</p> <p>20 you actually recite to the Schimpf 2014 systematic</p> <p>21 review as one of your case authorities.</p> <p>22 A Yes.</p> <p>23 Q And you said, "Overall the data show that</p> <p>24 rates of mesh exposure with TVT around one to two and</p>
<p style="text-align: right;">Page 27</p> <p>1 A That's correct.</p> <p>2 Q Now, the 800, that's the same 800 that</p> <p>3 you refer to, so what I'm reading here is that you</p> <p>4 have never had a single patient suffer from</p> <p>5 dyspareunia, pelvic pain, or mesh erosion. Is that</p> <p>6 right?</p> <p>7 A That's correct.</p> <p>8 Q And further down the page it says, "My</p> <p>9 patients go home the same day catheter-free, resume</p> <p>10 usual activities in 48 hours, and have immediate</p> <p>11 long-lasting cure."</p> <p>12 Do you see that?</p> <p>13 A I do.</p> <p>14 Q So what I hear when I hear this is that</p> <p>15 in your view proper technique results in a -- in your</p> <p>16 case, at least, a perfect record of objective and</p> <p>17 subjective success --</p> <p>18 MR. RUMANEK: Objection --</p> <p>19 BY MR. THOMPSON:</p> <p>20 Q -- in your patients. Is that right?</p> <p>21 MR. RUMANEK: Objection to form.</p> <p>22 THE WITNESS: I would say that technique</p> <p>23 plays a significant part in determining the</p> <p>24 patient's success and their risk of</p>	<p style="text-align: right;">Page 29</p> <p>1 a half percent and are manageable"; correct? That's</p> <p>2 what you said.</p> <p>3 A That's correct.</p> <p>4 Q Now, unfortunately I have only one copy</p> <p>5 of the Schimpf report with me, but hopefully you can</p> <p>6 -- well, I have not even thought of that. Maybe you</p> <p>7 brought it with you. Can you put your hand on it</p> <p>8 really quickly, or is that going to take too much</p> <p>9 time?</p> <p>10 A I think --</p> <p>11 MR. RUMANEK: It will not take some time.</p> <p>12 MR. THOMPSON: Super.</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q Now, this is an article. It is entitled</p> <p>15 "Sling Surgery For Stress Urinary Incontinence In</p> <p>16 Women: A Systematic Review and Meta-analysis" --</p> <p>17 A Uh-huh.</p> <p>18 Q -- correct?</p> <p>19 A Correct.</p> <p>20 Q Now, this is not a clinical trial, is it?</p> <p>21 A It is not.</p> <p>22 Q This is a -- in essence, it's a</p> <p>23 compilation and analysis of lots and lots of studies;</p> <p>24 correct?</p>

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<p>1 A Most that are clinical trials.</p> <p>2 Q Yes. But this paper itself is sort of a</p> <p>3 meta-analysis of the outcomes of those earlier</p> <p>4 studies?</p> <p>5 A That's correct.</p> <p>6 Q Now, the Schimpf in 2014, if I go to</p> <p>7 page 1 dot E11, do you see that? Where they actually</p> <p>8 write -- they say, "MUS versus Burch urethropexy"?</p> <p>9 A One dot E1? I'm sorry.</p> <p>10 Q One dot E11.</p> <p>11 A One dot E1 is what I see, and --</p> <p>12 Q The top of the page is table four. Okay.</p> <p>13 It's about the --</p> <p>14 MR. SKOLKY: It's the 11th page.</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q Yes, the 11th page. Good one.</p> <p>17 A Okay.</p> <p>18 Q And you see down in the discussion at the</p> <p>19 bottom it's MUS, and that would be mid-urethral sling;</p> <p>20 right?</p> <p>21 A Yes.</p> <p>22 Q Versus Burch urethropexy?</p> <p>23 A Yes.</p> <p>24 Q And it's hard to know what's taking</p>	<p>1 question just so that it's clear on the record?</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q Here is what I will do. Let me give you</p> <p>4 another question.</p> <p>5 A No. I can answer that question. What I</p> <p>6 am looking for is the follow-up time that was reported</p> <p>7 in this paper because in the short-term the Burch and</p> <p>8 mid-urethral slings do have equivalent efficacy. It's</p> <p>9 long-term where they differ. In the five-year success</p> <p>10 rate of a Burch is 24 percent as evidenced by the</p> <p>11 SISTEr trial. So short-term they are equivalent.</p> <p>12 Long-term they are not.</p> <p>13 Q The SISTEr trial was in 2007; is that</p> <p>14 right?</p> <p>15 A I don't remember.</p> <p>16 Q Let's see.</p> <p>17 A But even beyond that, the totality of the</p> <p>18 evidence and data supports the fact that the Burch has</p> <p>19 a lower success rate than mid-urethral slings, which</p> <p>20 is why that was a summary statement in the American</p> <p>21 College and American Urogynecologic joint positions --</p> <p>22 not position statement; practice bulletin about the</p> <p>23 treatment of stress incontinence in women where they</p> <p>24 state that a retropubic colposuspension has a greater</p>
Page 31	Page 33
<p>1 things out of context and what is surplusage, so let</p> <p>2 me just read the part that caught my eye, and that's</p> <p>3 the second paragraph under that subtopic.</p> <p>4 It says, "The evidence review did not</p> <p>5 support a difference between the two surgeries with</p> <p>6 regard to objective cure, subjective cure, quality of</p> <p>7 life, or sexual function outcomes. While eight</p> <p>8 studies provided data about cure outcomes, there were</p> <p>9 fewer studies evaluating quality of life and sexual</p> <p>10 function. Meta-analysis of objective cure did not</p> <p>11 show a significant difference for sling compared to</p> <p>12 Burch."</p> <p>13 And it goes on from there, but as of 2014</p> <p>14 it appears from this study, at least, that -- and this</p> <p>15 study, like I say, is sort of a meta-analysis of all</p> <p>16 the preceding studies. It looks like there is no</p> <p>17 change or difference in efficacy between the</p> <p>18 traditional correction and the mid-urethral sling; is</p> <p>19 that right?</p> <p>20 MR. RUMANEK: I'm going to object to the</p> <p>21 form of that question, which I think was about</p> <p>22 three pages long, probably.</p> <p>23 THE WITNESS: Give me a second.</p> <p>24 MR. RUMANEK: Can you restate the</p>	<p>1 risk of voiding dysfunction and a lower long-term</p> <p>2 success rate than mid-urethral slings, and that's</p> <p>3 supported by level A evidence.</p> <p>4 Q I'm trying to find the -- I'm still back</p> <p>5 trying to find this study that you have referred to.</p> <p>6 Is it in -- I thought it was in your -- I thought it</p> <p>7 was in your report, but I'm not seeing it. Which --</p> <p>8 tell me the name of it again. The 24 percent one?</p> <p>9 A Oh, SISTEr.</p> <p>10 Q SISTEr. All right. Well, is it in your</p> <p>11 report and I'm just not seeing it?</p> <p>12 A It is, somewhere.</p> <p>13 Q Help me get on it.</p> <p>14 A It might be before where we are. The</p> <p>15 Burch review. Retropubic -- the Burch procedure.</p> <p>16 Q I'm at the point where I would have</p> <p>17 expected to find it. This is the urethral suspension,</p> <p>18 although effective in the short-term, proven to have</p> <p>19 miserable long-term cure rates; Brubaker?</p> <p>20 A Yes.</p> <p>21 Q And Albo, but I don't see SISTEr. Okay.</p> <p>22 A I just saw it this morning, I thought.</p> <p>23 I'm not finding it either, and I forget the title.</p> <p>24 SISTEr is not in the title of the paper.</p>

<p style="text-align: right;">Page 34</p> <p>1 Q I see. You think it might be Brubaker 2 here? 3 A It's Brubaker. Where is that? 4 Q So that is 2006. 5 A Where? What page are you on? 6 Q I'm on page 6. Brubaker -- 7 MR. RUMANEK: Can we go off the record 8 just a second? 9 (Discussion ensued off the record.) 10 MR. RUMANEK: Let's go -- are we back? 11 BY MR. THOMPSON: 12 Q You refer to Albo right here on page 6. 13 It's right under Brubaker. Albo, Burch, 14 colposuspension versus fascial sling to reduce urinary 15 stress incontinence -- 16 A Yes. 17 Q -- 2007; right? 18 A That's correct. 19 Q And so that also was seven years earlier 20 than the Schimpf meta-analysis; correct? 21 A That's correct. 22 Q Let's get back on track. Those are the 23 sort of off-line questions that I had. Doctor, you've 24 commented and criticized several positions of</p>	<p style="text-align: right;">Page 36</p> <p>1 you've recited to Schimpf that shows an overall 2 exposure, mesh exposure of between one and two and a 3 half percent. 4 A What page are you looking at? 5 Q I'm looking at page 10, but I'm also 6 making reference to Schimpf as well. At the middle 7 of -- 8 A Yes. 9 Q -- the page it says, "Overall the data 10 shows rates of mesh exposure" -- 11 A Right. 12 Q -- "around one to 2.5 percent and are 13 manageable." 14 A Yes. 15 Q Okay? 16 A Yes. 17 Q Now, if I put the denominator for you at 18 800 and I put the numerator for you at zero, then 19 you're dragging down that one to two and a half 20 percent. Is somebody else out there having twice or 21 three times the number that is this average, or is 22 this expected? 23 MR. RUMANEK: Objection to the form of 24 the question.</p>
<p style="text-align: right;">Page 35</p> <p>1 plaintiffs in this case, and I want to go through and 2 look at them one by one, if I can. Okay? 3 A Okay. 4 Q And we've actually talked about the first 5 one and that is, we've looked at Schimpf and we see 6 that the objective and subjective cures of SUO, of 7 mid-urethral slings, is, according to the studies, 8 that there is no effective -- there is no difference 9 between the two, and you've stated, and that's over 10 the short run. Over the long run there is a 11 difference; correct? 12 MR. RUMANEK: Objection to form. 13 THE WITNESS: That's correct. 14 BY MR. THOMPSON: 15 Q Are there any follow-up studies that you 16 are aware of that continue to look at the long-term 17 outcomes of native tissue repair as opposed to a 18 mid-urethral sling? 19 A When you say native tissue, you are 20 referring to a Burch? 21 Q Yes, ma'am. 22 A No. There is no comparison studies that 23 looks long-term that I'm aware of. 24 Q Now, you've recited and you've looked and</p>	<p style="text-align: right;">Page 37</p> <p>1 THE WITNESS: No. But I think a lot of 2 that goes to what you were getting at 3 earlier -- 4 BY MR. THOMPSON: 5 Q Yes. 6 A -- in terms of experience -- 7 Q Yes. 8 A -- and having better success -- 9 Q Yeah. 10 A -- the longer that you do something. I 11 started doing slings when I was a resident, so I've 12 been doing them now for 16 years. 13 Q Yes. 14 A So this -- these, you know, 800 cases 15 include mostly that latter part. You know, there may 16 be 20 or 30 cases in residency and fellowship, but 17 even then at least while I was in residency and 18 fellowship, I didn't see any patients that had mesh 19 erosion or dyspareunia. But part of that I believe 20 too is because I've been trained. I've trained in 21 residency conditions and trained by the person that 22 did the first TVT in the country, trained at one of 23 the best surgical training programs in the country, so 24 I think that makes a difference.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q Would you say that the competence, skill, 2 and experience of the implanting doctor is important 3 to the successful outcome of the procedure? 4 A Yes. 5 Q Have you ever served as a faculty member 6 at any of these medical device company trainings? 7 A No. 8 Q I mean, has Ethicon ever come to you and 9 said, oh, we want you to fly out to Las Vegas and do 10 our 24-hour cadaver training for 12 people? 11 A I may have been approached at some point 12 in my career, but I've never actually served as a 13 proctor, no. 14 Q Have you ever actually attended one of 15 these training sessions? 16 A For the TVT? 17 Q Yes, ma'am. 18 A No, not that I recall. 19 Q Well, how about for something else, then? 20 A Oh, yes. 21 Q And what? What were the other products 22 that you have attended a training for? 23 MR. RUMANEK: Any product generally, or 24 are you talking --</p>	<p style="text-align: right;">Page 40</p> <p>1 looking for an alternative to the Prolift once that 2 was taken off the market. 3 Q Yes. 4 A And I felt it was important to have 5 apical and distal suspension. I felt like it was 6 important to not draw the anterior vaginal wall down 7 with a sacrospinous fixation, so I felt like what I 8 was seeing wasn't as optimal as what I had been using. 9 Q Did you feel like after you went to the 10 cadaver lab, that you were competent to go and perform 11 those procedures? 12 A I -- I do. It wasn't necessarily just 13 the cadaver lab, but my background as well. I had 14 been doing those dissections. I'd been trained to do 15 vaginal mesh implantation, trained to do mid-urethral 16 slings, and so the dissections really aren't that 17 different. So I have a lot of experience coming to 18 that cadaver lab that others may not and -- but I did 19 feel pretty confident. 20 But I would still probably want someone 21 who was very comfortable with those procedures to, you 22 know, kind of come and, you know, go see them and make 23 sure that I'm comfortable with everything. Everything 24 has a little bit of nuance to it.</p>
<p style="text-align: right;">Page 39</p> <p>1 MR. THOMPSON: Yes. 2 MR. RUMANEK: -- about Ethicon 3 specifically? 4 MR. THOMPSON: Well, any product 5 generally. 6 THE WITNESS: Oh, wow. I've been to a 7 cadaver lab for Elevate, which is a vaginal 8 mesh procedure. 9 BY MR. THOMPSON: 10 Q Yes. 11 A I've been to a cadaver lab for -- what 12 was the name of that? The Boston Scientific product. 13 The -- Uphold, I believe it was called. 14 Q Yes. 15 A And I have been to a cadaver lab on -- I 16 forget what it's called. I think it's called Altis, 17 the mini sling, single-incision sling. 18 Q After you attended those did you utilize 19 those products in your practice on your patients? 20 A No. 21 Q Why not? 22 A I felt like there were weaknesses in -- 23 that I -- I didn't feel like they were as 24 comprehensive. I'd been using the Prolift, and I was</p>	<p style="text-align: right;">Page 41</p> <p>1 Q I see. Do you serve as a mentor or a 2 proctor for doctors at Kaiser who are new to a 3 procedure? 4 A I have. 5 Q And is that the way you think it ought to 6 go? That you -- somebody sits in with you and 7 observes you or assists you and -- 8 MR. RUMANEK: Objection to form. 9 BY MR. THOMPSON: 10 Q -- gains confidence and competence? 11 MR. RUMANEK: Objection to the form of 12 the question. 13 THE WITNESS: Oh, in -- I guess I'm not 14 sure about if you're -- are you asking, do I 15 think that should be regulated? Do I think it 16 should be mandated? Or what do you mean by do 17 you think I -- 18 BY MR. THOMPSON: 19 Q Well, let's start with, is it a good 20 idea? 21 A I think that's up to the surgeon and the 22 surgeon's level of comfort. 23 Q And so you've actually answered the 24 second question. That is, should it be dictated or</p>

<p style="text-align: right;">Page 42</p> <p>1 regulated? You would leave that to the surgeon's</p> <p>2 comfort; is that right?</p> <p>3 A That's correct. Outside of normal</p> <p>4 credentialing, yes.</p> <p>5 Q Now, Doctor, you were not -- you've given</p> <p>6 an opinion with regard to the -- within your report</p> <p>7 about the polypropylene itself. Do you intend at</p> <p>8 trial to give an opinion on the characteristics of</p> <p>9 polypropylene in the body?</p> <p>10 A If I'm asked.</p> <p>11 Q And here I guess these are going to be my</p> <p>12 questions, then. Are you a materials scientist?</p> <p>13 A I'm a scientist, and so I'm able to</p> <p>14 evaluate published literature, whether it's about</p> <p>15 materials or whether it's about clinical outcomes or</p> <p>16 something else.</p> <p>17 Q And have you worked with polymer</p> <p>18 chemicals in your career in terms of analyzing them,</p> <p>19 analyzing their characteristics, their strengths,</p> <p>20 their weaknesses?</p> <p>21 A No.</p> <p>22 Q Have you conducted any tests on the</p> <p>23 polypropylene materials that constitute or that make</p> <p>24 up a TVT device?</p>	<p style="text-align: right;">Page 44</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Have you had patients that have come to</p> <p>3 you with exposure or erosions?</p> <p>4 A Yes.</p> <p>5 Q And have you diagnosed and formed a plan</p> <p>6 of treatment that includes resection or removal of the</p> <p>7 mesh?</p> <p>8 A Sometimes.</p> <p>9 Q And do you perform that surgery yourself?</p> <p>10 A I do.</p> <p>11 Q How many resections or revisions have you</p> <p>12 performed?</p> <p>13 A I would have to guess. Approximately</p> <p>14 six, maybe.</p> <p>15 Q Have you ever revised or resected a TVT</p> <p>16 mesh?</p> <p>17 A Not that I can recall. I have resected</p> <p>18 mid-urethral slings, but none of them have been the</p> <p>19 TVT.</p> <p>20 Q I see. And can you recall the symptoms</p> <p>21 that were being displayed by the patient that required</p> <p>22 the resection or the revision?</p> <p>23 A Usually it's vaginal spotting or bleeding</p> <p>24 or male partner dyspareunia, and sometimes voiding</p>
<p style="text-align: right;">Page 43</p> <p>1 MR. RUMANEK: Objection to the form of</p> <p>2 the question.</p> <p>3 THE WITNESS: No.</p> <p>4 BY MR. THOMPSON:</p> <p>5 Q Have you -- oh, let me ask it this way.</p> <p>6 Have you participated in explanting polypropylene mesh</p> <p>7 from your patients?</p> <p>8 MR. RUMANEK: Objection to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. THOMPSON:</p> <p>11 Q And certainly you are not explanting your</p> <p>12 own patients because none of them have ever needed it</p> <p>13 explanted, but how would that patient come to you?</p> <p>14 A Usually it's a patient who has either</p> <p>15 switched insurances or is no longer seeing the doctor</p> <p>16 that did their implant, so they come to me with the</p> <p>17 desire to resolve their complications.</p> <p>18 Q And are there patients that have come to</p> <p>19 you with erosions or exposures?</p> <p>20 MR. RUMANEK: Object to the form. Are</p> <p>21 you talking specifically about TVTs, or are you</p> <p>22 talking about across the board?</p> <p>23 MR. THOMPSON: Well, actually let's talk</p> <p>24 about all polypropylene mesh.</p>	<p style="text-align: right;">Page 45</p> <p>1 dysfunction and irritative symptoms.</p> <p>2 Q When you perform the resection do you</p> <p>3 remove the entire polypropylene device?</p> <p>4 A Not usually, no.</p> <p>5 Q And what happens to the remnants of the</p> <p>6 device or what's left after you resect what you are</p> <p>7 going to resect?</p> <p>8 A It just remains in place.</p> <p>9 Q Now, when you resect the device, is there</p> <p>10 innervation by living material into the mesh?</p> <p>11 MR. RUMANEK: Objection to the form of</p> <p>12 the question.</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q I mean, is there a -- let me strike that.</p> <p>15 Is there ingrowth? Has the living tissue grown into</p> <p>16 and through the pores of the mesh?</p> <p>17 MR. RUMANEK: Objection to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. THOMPSON:</p> <p>20 Q And of course that's the way it's</p> <p>21 designed; right? It's designed to encourage an</p> <p>22 inflammatory response, which causes ingrowth through</p> <p>23 the pores --</p> <p>24 MR. RUMANEK: Objection --</p>

<p style="text-align: right;">Page 46</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q -- isn't that right?</p> <p>3 A It encourages fibroblast and collagen</p> <p>4 ingrowth and deposition.</p> <p>5 Q So when you go to remove it, you're not</p> <p>6 simply sliding -- you're not sliding that mesh out</p> <p>7 like unsheathing a sword? You're having to cut it</p> <p>8 out; isn't that right?</p> <p>9 A That's correct.</p> <p>10 Q And do you stitch it after you cut it, or</p> <p>11 is it simply left to grow back together again by</p> <p>12 contact between the two sides?</p> <p>13 MR. RUMANEK: Objection to form of the</p> <p>14 question.</p> <p>15 THE WITNESS: It doesn't grow back</p> <p>16 together again.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q Yes.</p> <p>19 A When the sling is placed, it -- we call</p> <p>20 it a Velcro effect. Once the plastic sheath is</p> <p>21 removed, it stays in place and the tissue grows into</p> <p>22 it where it is, so when you are cutting or excising a</p> <p>23 portion of it, the part that remains, stays in its</p> <p>24 original position pretty much.</p>	<p style="text-align: right;">Page 48</p> <p>1 formation.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q Yes.</p> <p>4 A I don't usually see a scar plate in what</p> <p>5 I would think that to be, so no.</p> <p>6 Q And when you take the part, the section</p> <p>7 out, do you participate in the pathology analysis of</p> <p>8 the removed section?</p> <p>9 MR. RUMANEK: Objection to form.</p> <p>10 THE WITNESS: I don't.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q You don't participate either in the gross</p> <p>13 or the microscopic inspection of the removed section;</p> <p>14 is that right?</p> <p>15 MR. RUMANEK: Objection to form.</p> <p>16 THE WITNESS: That's correct.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q Now, have you done any work on the</p> <p>19 properties of the polypropylene itself? For example,</p> <p>20 rates of oxidation or degradation?</p> <p>21 MR. RUMANEK: Objection to form. Are you</p> <p>22 limiting it those things?</p> <p>23 MR. THOMPSON: Yes, sir.</p> <p>24 THE WITNESS: When you say work, what do</p>
<p style="text-align: right;">Page 47</p> <p>1 Q I see. I see. Now, if there was a</p> <p>2 portion of the sling that was causing discomfort,</p> <p>3 that's the part that has to come out; right?</p> <p>4 MR. RUMANEK: Objection to the form of</p> <p>5 the question.</p> <p>6 THE WITNESS: If there is a portion of</p> <p>7 the sling causing discomfort, is that the part</p> <p>8 that has to come out? That's not really a</p> <p>9 yes-or-no question. Most of the time if</p> <p>10 patients are having pain from mesh</p> <p>11 augmentation, whether it be a sling or vaginal</p> <p>12 mesh, it's because the mesh is on tension, and</p> <p>13 relieving the tension usually relieves the</p> <p>14 pain.</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q I see. When you go -- in these six</p> <p>17 revision operations that you have performed, when you</p> <p>18 performed those six operations was the mesh or the</p> <p>19 scar plate with the mesh sort of encased in it, did it</p> <p>20 show evidence of contracture?</p> <p>21 MR. RUMANEK: Objection to the form of</p> <p>22 the question and the characterization.</p> <p>23 THE WITNESS: Type one polypropylene mesh</p> <p>24 to my knowledge, doesn't cause scar plate</p>	<p style="text-align: right;">Page 49</p> <p>1 you mean?</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q I mean have you performed any testing?</p> <p>4 A No.</p> <p>5 Q Have you participated in any kind of</p> <p>6 trials in which you would implant polypropylene</p> <p>7 material and then excise it and look and see what had</p> <p>8 happened --</p> <p>9 MR. RUMANEK: Object --</p> <p>10 BY MR. THOMPSON:</p> <p>11 Q -- while it was implanted?</p> <p>12 MR. RUMANEK: Objection to the form of</p> <p>13 the question.</p> <p>14 THE WITNESS: No. But I don't need to,</p> <p>15 to be able to read the results of the people</p> <p>16 that have --</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q Right.</p> <p>19 A -- and those results have been</p> <p>20 published --</p> <p>21 Q So --</p> <p>22 A -- for the community to evaluate, and</p> <p>23 there has not been any significant clinical data to</p> <p>24 support degradation or oxidation or scar plating or</p>

<p style="text-align: right;">Page 50</p> <p>1 anything like that with macroporous type one</p> <p>2 polypropylene mesh.</p> <p>3 THE REPORTER: I'm sorry. With the?</p> <p>4 THE WITNESS: With macroporous.</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q And what do you define macroporous as?</p> <p>7 A There have been two definitions that have</p> <p>8 been used.</p> <p>9 Q Right.</p> <p>10 A Over 75 micrograms is what we classify as</p> <p>11 macroporous as it relates to infection risk. Over one</p> <p>12 millimeter is what we refer to in terms of -- what's</p> <p>13 the right word? -- stiffness.</p> <p>14 Q Now, both of those numbers, you have</p> <p>15 derived them by reading them; is that right?</p> <p>16 MR. RUMANEK: Objection to form.</p> <p>17 THE WITNESS: That's correct.</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q You have not done any experimentation on</p> <p>20 the proper pore size to encourage ingrowth, have you?</p> <p>21 MR. RUMANEK: Objection.</p> <p>22 THE WITNESS: I have not.</p> <p>23 BY MR. THOMPSON:</p> <p>24 Q Now, with regard -- there is a phenomenon</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Now, with regard to -- we've talked about</p> <p>3 the 75. How about, Doctor, have you done any research</p> <p>4 into whether polypropylene is inert in the human body?</p> <p>5 A What do you mean by research?</p> <p>6 Q I mean, have you performed any --</p> <p>7 performed any research in which you physically tested</p> <p>8 the reactivity or the inertness of polypropylene in</p> <p>9 the human body?</p> <p>10 A No.</p> <p>11 Q And so your information with regard to</p> <p>12 the inertness or reaction would be a result of your</p> <p>13 reading the literature on it; is that right?</p> <p>14 MR. RUMANEK: I don't think that's a fair</p> <p>15 characterization. Objection to form.</p> <p>16 THE WITNESS: My opinion about that is</p> <p>17 based on my review of the literature, my</p> <p>18 clinical experience with my 800 sling patients,</p> <p>19 my clinical experience with the 1,200 patients</p> <p>20 or so that I have implanted polypropylene mesh,</p> <p>21 and the literature that states that 3 million</p> <p>22 women have been implanted with mid-urethral</p> <p>23 slings and have had excellent success --</p> <p>24 BY MR. THOMPSON:</p>
<p style="text-align: right;">Page 51</p> <p>1 known as roping. Are you familiar with roping?</p> <p>2 A I think I know what you're talking about</p> <p>3 with roping.</p> <p>4 Q Well, let me say it in another way. If</p> <p>5 you tug on a polypropylene mesh, it decreases in</p> <p>6 diameter and forms a more solid or a thinner lining</p> <p>7 all the way down to where if you actually pull on it</p> <p>8 pretty good, you end up with a single edge, and that</p> <p>9 phenomenon is known as roping. Are you familiar with</p> <p>10 that, where it loses diameter?</p> <p>11 A I've read that.</p> <p>12 Q Have you performed any experiments</p> <p>13 yourself on that phenomenon?</p> <p>14 MR. RUMANEK: Objection to form.</p> <p>15 THE WITNESS: No.</p> <p>16 MR. RUMANEK: Fred, we've been going for</p> <p>17 an hour.</p> <p>18 MR. THOMPSON: Yes.</p> <p>19 MR. RUMANEK: Want to take a couple of</p> <p>20 minutes to --</p> <p>21 MR. THOMPSON: That would be great.</p> <p>22 MR. RUMANEK: -- and stretch legs.</p> <p>23 MR. THOMPSON: That would be great.</p> <p>24 (A recess was taken.)</p>	<p style="text-align: right;">Page 53</p> <p>1 Q All right.</p> <p>2 A -- with minimal maleffects, and the fact</p> <p>3 that polypropylene is standard of care for fascial</p> <p>4 replacement, not just with female pelvic</p> <p>5 reconstructive surgery, but with general surgery, with</p> <p>6 otolaryngology, with any surgical procedure where</p> <p>7 fascia has to be replaced with a synthetic,</p> <p>8 polypropylene is that -- is that choice, in addition</p> <p>9 to the fact that we have been using Prolene suture for</p> <p>10 50-plus years, et cetera.</p> <p>11 Q Well, now, your clinical experience,</p> <p>12 you've put it in 800 plus 1,300 -- you put it in 2,100</p> <p>13 times, but you've only taken it out six; is that</p> <p>14 right?</p> <p>15 A That's correct.</p> <p>16 Q So you have only seen six of them after</p> <p>17 they've been in the body; isn't that right?</p> <p>18 MR. RUMANEK: Objection to the form of</p> <p>19 the question.</p> <p>20 BY MR. THOMPSON:</p> <p>21 Q I guess I'm exploring what you mean by</p> <p>22 clinical experience.</p> <p>23 A My clinical experience using the product,</p> <p>24 using polypropylene.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q Yes. Okay. But like I say, what you are</p> <p>2 saying is that I've put it in 800 plus 1,300 times and</p> <p>3 I'm unaware of what -- it must work because I haven't</p> <p>4 had any complaints about it. That's your clinical</p> <p>5 experience?</p> <p>6 MR. RUMANEK: Objection to form.</p> <p>7 THE WITNESS: That's not -- I don't just</p> <p>8 put it in and walk away. I see my patients</p> <p>9 back in postop follow-up. They come to see me</p> <p>10 at two weeks, six weeks, six months, three</p> <p>11 months. You know, I see them and follow them,</p> <p>12 their course and how they tolerate the</p> <p>13 polypropylene, and they do very well.</p> <p>14 BY MR. THOMPSON:</p> <p>15 Q So you are seeing -- you're getting a</p> <p>16 sense of the -- how they're tolerating it by their</p> <p>17 symptoms and by your external examination; is that</p> <p>18 right?</p> <p>19 A That's correct.</p> <p>20 Q So with regard to whether it's oxidizing</p> <p>21 or reacting, your source for that would be if somebody</p> <p>22 complained about it; is that right?</p> <p>23 MR. RUMANEK: Are you limiting that to</p> <p>24 clinically, her clinical experience?</p>	<p style="text-align: right;">Page 56</p> <p>1 of the literature; isn't that right?</p> <p>2 MR. RUMANEK: Along with the other things</p> <p>3 that she mentioned when she answered a few</p> <p>4 minutes ago.</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q Well, as I understand it, the other</p> <p>7 things were also literature. It's position papers and</p> <p>8 things like that. I mean, it's all from what you have</p> <p>9 read and you've --</p> <p>10 A I guess what I am trying to communicate</p> <p>11 is that if there was a condition that was affecting</p> <p>12 the mesh that would cause a complication, whether that</p> <p>13 be oxidation, degradation, or any of those things,</p> <p>14 that I would have some clinical evidence of that in my</p> <p>15 patients.</p> <p>16 Q I see. Well, okay. All right. Your</p> <p>17 statement that there is no reliable scientific data</p> <p>18 that shows that increasing the pore size of TVT would</p> <p>19 increase efficacy or lower complications without</p> <p>20 impairing the utility of the TVT?</p> <p>21 MR. RUMANEK: Fred, what page are you on?</p> <p>22 MR. THOMPSON: I'm on page 14. I'm</p> <p>23 sorry. The final paragraph. I think this is</p> <p>24 opinion Number 3. Actually, that's just my own</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Well, yeah because I thought we were</p> <p>3 dealing with her reading the literature, which I'm</p> <p>4 perfectly happy for you to answer that, but you're</p> <p>5 saying that your clinical experience is one of the</p> <p>6 bases for that opinion, and I need to understand the</p> <p>7 extent of your clinical experience. I think I</p> <p>8 understand it, but I just want to make sure. I mean,</p> <p>9 you don't --</p> <p>10 A I --</p> <p>11 Q -- go to them and say, oh, you're doing</p> <p>12 fine, so let me go in and biopsy the polypropylene so</p> <p>13 that I can test it? I mean, nobody has ever done</p> <p>14 that, have they?</p> <p>15 A That's correct.</p> <p>16 Q So you see your patients on follow-up,</p> <p>17 and if they're doing fine, then you extrapolate from</p> <p>18 that, that the polypropylene is intact and doing its</p> <p>19 job; correct?</p> <p>20 A That's correct.</p> <p>21 Q But as far as you actually performing</p> <p>22 tests on whether it's inert or whether it's oxidizing</p> <p>23 or whether it's reacting to certain types of agents</p> <p>24 within the body, your source for that is your review</p>	<p style="text-align: right;">Page 57</p> <p>1 wording.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q And here again I think this is a little</p> <p>4 bit plowing the same ground again, but the pore size,</p> <p>5 your source of information that forms the basis of</p> <p>6 your opinion is your review of the literature; is that</p> <p>7 right?</p> <p>8 MR. RUMANEK: Object to form. I don't</p> <p>9 think that's consistent with the way she</p> <p>10 testified.</p> <p>11 MR. THOMPSON: Well, no. Now I'm talking</p> <p>12 about pore size.</p> <p>13 MR. RUMANEK: Well, okay.</p> <p>14 THE WITNESS: So --</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q No. Let me make sure because I'm often</p> <p>17 not descript -- we were just talking about oxidation,</p> <p>18 and you talked about one of the bases for your opinion</p> <p>19 was clinical experience --</p> <p>20 A Yes.</p> <p>21 Q -- and we went through that. I'm now</p> <p>22 asking specifically about pore size, your statement</p> <p>23 that there is no evidence that increasing the pore</p> <p>24 size would create a safer or more efficacious product,</p>

<p style="text-align: right;">Page 58</p> <p>1 and that's how I'm reading this third opinion here.</p> <p>2 And my question is, the basis -- I'm exploring the</p> <p>3 basis for that opinion, and all I'm reading within</p> <p>4 your report is that you have reviewed the literature</p> <p>5 and concluded that that is what is supported by the</p> <p>6 literature.</p> <p>7 MR. RUMANEK: Well, why don't you ask her</p> <p>8 the basis for her opinion?</p> <p>9 MR. THOMPSON: Well, that's what I was</p> <p>10 leading up to.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q Do you have any other basis other than</p> <p>13 your review of the literature, for making the</p> <p>14 statement that there is no evidence that increasing</p> <p>15 the pore size would help safety or efficacy?</p> <p>16 A Yes.</p> <p>17 Q What is that?</p> <p>18 A So again, my clinical experience, the</p> <p>19 experience of my colleagues, the experience of the</p> <p>20 international community has been that the TVT in its</p> <p>21 current shape and form is extremely effective and well</p> <p>22 tolerated with a mesh erosion rate of one to</p> <p>23 two percent, dyspareunia rate of three to</p> <p>24 four percent. I mean, the incidence of complications</p>	<p style="text-align: right;">Page 60</p> <p>1 between 100 and a thousand times, once in a 100 to a</p> <p>2 thousand, it's referred to as not uncommon, and if</p> <p>3 it's between 1,000 and 10,000, it uncommon, and over</p> <p>4 10,000 it's rare. Have you ever heard that?</p> <p>5 A I haven't.</p> <p>6 Q Well, then we'll move on. But the rates</p> <p>7 that you're describing, one to two percent and two to</p> <p>8 four percent, to somebody who's never had a bad one,</p> <p>9 aren't those high to you?</p> <p>10 MR. RUMANEK: Objection --</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q I mean, doesn't that mean that there is</p> <p>13 somebody out there not doing a good job?</p> <p>14 MR. RUMANEK: Objection to form.</p> <p>15 THE WITNESS: No, that's not high to me.</p> <p>16 BY MR. THOMPSON:</p> <p>17 Q Oh, okay. But to somebody who's perched</p> <p>18 on zero complications, one to two plus two to four, I</p> <p>19 guess we're talking about three to six percent</p> <p>20 total --</p> <p>21 A These are international rates, in the</p> <p>22 hands of all comers. That's exceedingly low. I'm a</p> <p>23 board-certified fellowship-trained female pelvic</p> <p>24 reconstructive surgeon, so I have specific expertise,</p>
<p style="text-align: right;">Page 59</p> <p>1 is already so low, it would be difficult to improve on</p> <p>2 that.</p> <p>3 Q Yes.</p> <p>4 A So that's Number 1. Number 2, when we</p> <p>5 have looked at larger pore-sized meshes like Vypro</p> <p>6 when they have been utilized in pelvic reconstructive</p> <p>7 surgery, they have had sometimes more complications</p> <p>8 than meshes of smaller pore size, so we don't have any</p> <p>9 evidence to suggest that increasing the pore size of</p> <p>10 the TVT would make it more effective or decrease its</p> <p>11 complication rate.</p> <p>12 Q I see. Now, when you talk about the</p> <p>13 complication rate being low, are you aware that there</p> <p>14 is actually a nomenclature for complication rates in</p> <p>15 pharmaceutical arenas?</p> <p>16 MR. RUMANEK: Objection to form.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q That the words that we use in lay</p> <p>19 parlance actually have an epidemiological aspect to</p> <p>20 them. Are you aware of that?</p> <p>21 A Not as it relates to pharmaceuticals, no.</p> <p>22 Q Well, for example, if there is a</p> <p>23 complication that happens more than once every 100</p> <p>24 times, it's referred to as common. If it happens</p>	<p style="text-align: right;">Page 61</p> <p>1 and this is all I do. That -- those numbers are the</p> <p>2 case for gynecologists, urologists, people that may</p> <p>3 not have been fellowship trained. So to have, you</p> <p>4 know, numbers that we ascertain from 81 randomized</p> <p>5 control trials and 12,000 patients, to have a rate of</p> <p>6 one percent, I think that's very low.</p> <p>7 Q I guess I continue to be fascinated by</p> <p>8 this. How does the poor patient out in the community</p> <p>9 know that if she comes to you she's getting a person</p> <p>10 with a complication rate of zero and if she goes to</p> <p>11 poor old Dr. Perlow she's getting a complication rate</p> <p>12 of 20 percent? I mean, that's just potluck?</p> <p>13 MR. RUMANEK: Objection to form.</p> <p>14 THE WITNESS: I mean, it is what it is.</p> <p>15 That's the way it is. I mean --</p> <p>16 MR. RUMANEK: I don't even understand</p> <p>17 what the question is. What is your question?</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q My question is, does -- well, let me just</p> <p>20 ask it this way. In the middle of all of these</p> <p>21 position papers and statements have you ever seen a</p> <p>22 statement by AUGS that patients should be advised of</p> <p>23 the complication rate of the surgeon and should be</p> <p>24 directed to competent fellowship-trained surgeons for</p>

<p style="text-align: right;">Page 62</p> <p>1 performing this operation? Have you ever seen any</p> <p>2 statement by these guys that that's what should --</p> <p>3 that's what patients should be entitled to?</p> <p>4 MR. RUMANEK: It's a very specific --</p> <p>5 objection to the form of the question;</p> <p>6 compound.</p> <p>7 THE WITNESS: AUGS has actually issued a</p> <p>8 patient tool kit as it relates to vaginal mesh</p> <p>9 and have given them a list of questions to ask</p> <p>10 their surgeon, and that list of questions does</p> <p>11 include how many of these cases have you done?</p> <p>12 What are your complications rates? And if I</p> <p>13 were to have a complication would you be</p> <p>14 handling it or would somebody else be handling</p> <p>15 it? So they have, you know, encouraged</p> <p>16 patients to ask those questions.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q Well, is there any activity by AUGS to</p> <p>19 police its ranks to ensure that patients get good</p> <p>20 surgeons and not bad surgeons?</p> <p>21 MR. RUMANEK: Objection to form, the</p> <p>22 characterization.</p> <p>23 THE WITNESS: No, and that's not their</p> <p>24 job to do that. I think what the evidence</p>	<p style="text-align: right;">Page 64</p> <p>1 question. Are you asking her about the TVT?</p> <p>2 MR. THOMPSON: Yes.</p> <p>3 THE WITNESS: Mrs. Bailey --</p> <p>4 MR. RUMANEK: Hold it. I don't think</p> <p>5 he's asking you about Miss Bailey anymore. I</p> <p>6 just want to make sure you-all two are on the</p> <p>7 same page.</p> <p>8 THE WITNESS: So when we say safe and</p> <p>9 effective, we're saying that the patient had a</p> <p>10 procedure that didn't cause hemorrhage, that</p> <p>11 didn't cause pulmonary embolism, that did not</p> <p>12 cause her any major morbidity. Mrs. Bailey had</p> <p>13 that. She had a procedure that was effective</p> <p>14 at treating her stress incontinence. She</p> <p>15 doesn't have stress incontinence. Did she have</p> <p>16 a maloccurrence with voiding dysfunction? Yes,</p> <p>17 she did. Was that corrected? Yes, it was. So</p> <p>18 did Miss Bailey have a safe and effective</p> <p>19 procedure? Yes.</p> <p>20 BY MR. THOMPSON:</p> <p>21 Q We keep coming back to Miss Bailey.</p> <p>22 That's because --</p> <p>23 MR. RUMANEK: I'm trying not to. I think</p> <p>24 the question is --</p>
<p style="text-align: right;">Page 63</p> <p>1 supports is that in the hand of all surgeons</p> <p>2 the mid-urethral sling is safe and effective.</p> <p>3 BY MR. THOMPSON:</p> <p>4 Q If Dr. Perlow is having a ten to</p> <p>5 20 percent complication rate, is that TVT for Miss</p> <p>6 Bailey safe and effective?</p> <p>7 MR. RUMANEK: Objection to form of the</p> <p>8 question.</p> <p>9 THE WITNESS: Mrs. Bailey suffered</p> <p>10 voiding.</p> <p>11 MR. RUMANEK: Well, hold on just a</p> <p>12 second. Are you asking a question specifically</p> <p>13 about Miss Bailey, or is this a general -- I</p> <p>14 mean --</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q Well, I'm using Miss Bailey as an</p> <p>17 example. Let's say Dr. X has a complication rate of</p> <p>18 20 percent. Is your statement that the TVT is safe</p> <p>19 and effective when used on patient Y by Dr. X, or do</p> <p>20 you still stand by that statement?</p> <p>21 A Absolutely.</p> <p>22 Q And is she just collateral damage? Is</p> <p>23 she chopped liver?</p> <p>24 MR. RUMANEK: Objection to form of the</p>	<p style="text-align: right;">Page 65</p> <p>1 MR. THOMPSON: Well, that's the only one</p> <p>2 that I'm interested in is Miss Bailey, so I'm</p> <p>3 not unhappy with that, but Eric is exactly</p> <p>4 right: We are a little bit premature talking</p> <p>5 about Miss Bailey.</p> <p>6 THE WITNESS: Okay.</p> <p>7 BY MR. THOMPSON:</p> <p>8 Q But here is my question. Let's ask it</p> <p>9 this way. Say you have a nail gun. Are you familiar</p> <p>10 with what a nail gun is?</p> <p>11 A Yes.</p> <p>12 Q And say there is a device on that nail</p> <p>13 gun that requires every time you pull the trigger,</p> <p>14 that one nail comes out and it requires you to pull</p> <p>15 the trigger; right?</p> <p>16 A Uh-huh.</p> <p>17 Q In the hands of a competent roofer, that</p> <p>18 is an impediment, and what the competent roofer really</p> <p>19 wants to do is to use it in an automatic mode, where</p> <p>20 it can fire multiple times every time you hit it.</p> <p>21 Okay?</p> <p>22 A Okay.</p> <p>23 Q Are you familiar with that?</p> <p>24 A No.</p>

<p style="text-align: right;">Page 66</p> <p>1 Q Well, and so 98 times out of 100 -- 98</p> <p>2 roofers out of 100 are out there having a great time</p> <p>3 because they have a brand of nail gun that allows them</p> <p>4 to fire at an infinite rate and they can work very</p> <p>5 quickly and very efficiently. Two guys out of 100</p> <p>6 shoot themselves in the hand. Okay? Here is my</p> <p>7 question. Is the nail gun defective, or is the nail</p> <p>8 gun just effective but used by incompetent roofers?</p> <p>9 MR. RUMANEK: Just a second. I need to</p> <p>10 object to the form of that question, the</p> <p>11 characterizations that call for legal</p> <p>12 conclusions. It's a completely improper</p> <p>13 hypothetical question.</p> <p>14 THE WITNESS: You lost me.</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q Here is my question. If a company knows</p> <p>17 that its device needs to be used by competent,</p> <p>18 well-trained physicians in order to be safe and</p> <p>19 effective, does not the company have the obligation to</p> <p>20 make sure that its product is used by competent,</p> <p>21 well-trained physicians?</p> <p>22 MR. RUMANEK: I'm going to object to the</p> <p>23 form of the question. It calls for a legal</p> <p>24 conclusion; calls for her to speculate about</p>	<p style="text-align: right;">Page 68</p> <p>1 physicians and medical devices.</p> <p>2 THE WITNESS: Okay. Let me just repeat</p> <p>3 the question to make sure I understand what you</p> <p>4 are asking me. Should a company go out and</p> <p>5 recruit incompetent people?</p> <p>6 BY MR. THOMPSON:</p> <p>7 Q Sure. That's a good --</p> <p>8 A Yeah -- no.</p> <p>9 Q -- start. Should a company go out and</p> <p>10 recruit people who have no background and undertake to</p> <p>11 train them?</p> <p>12 MR. RUMANEK: Objection to the form of</p> <p>13 the question to the extent -- same basis.</p> <p>14 THE WITNESS: Well, what do you mean by</p> <p>15 no background?</p> <p>16 BY MR. THOMPSON:</p> <p>17 Q If they have not performed mesh surgery</p> <p>18 before and now they undertake to train them to perform</p> <p>19 mesh surgery.</p> <p>20 A I don't think a company can determine who</p> <p>21 is competent or not competent to perform procedures.</p> <p>22 They have to make sure that their procedure is safe</p> <p>23 and effective in the general population, and it's up</p> <p>24 to the surgeon to decide what they're competent at</p>
<p style="text-align: right;">Page 67</p> <p>1 the obligation a hypothetical company has.</p> <p>2 THE WITNESS: No.</p> <p>3 BY MR. THOMPSON:</p> <p>4 Q What if the company actually goes out and</p> <p>5 solicits and attempts to attract physicians who may</p> <p>6 not have the competence or training to properly</p> <p>7 install its device? Does that change your thought at</p> <p>8 all?</p> <p>9 MR. RUMANEK: Objection to the form of</p> <p>10 the question on the same grounds.</p> <p>11 THE WITNESS: Could you repeat the</p> <p>12 question?</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q What if the company actually goes out and</p> <p>15 recruits physicians that may not have proper training</p> <p>16 or background to properly install the device?</p> <p>17 MR. RUMANEK: A --</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q Does that change your mind with regard to</p> <p>20 the company's obligation?</p> <p>21 MR. RUMANEK: Objection to the form of</p> <p>22 the question to the extent that the question is</p> <p>23 asking for her to speculate about what a</p> <p>24 company's obligation is with respect to</p>	<p style="text-align: right;">Page 69</p> <p>1 doing.</p> <p>2 Q Doctor, if I go to page 16, I see that</p> <p>3 you have stated it's speculation that -- or not spec</p> <p>4 -- that's Freudian. An opinion that it's my</p> <p>5 understanding that there has been a claim that the</p> <p>6 particles from the mechanically cut mesh can lead to</p> <p>7 complication like pain and erosion.</p> <p>8 Now, I guess my question is, I'd like to</p> <p>9 explore the basis for that opinion. Is that a review</p> <p>10 of literature, or what? What is your basis for that</p> <p>11 opinion?</p> <p>12 MR. RUMANEK: That it's her understanding</p> <p>13 that that's been claimed in the litigation?</p> <p>14 What? Sorry. I just want to make sure. I</p> <p>15 don't know what opinion you're asking about.</p> <p>16 MR. THOMPSON: I guess I should have read</p> <p>17 that.</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q Your opinion is, this is speculation</p> <p>20 without scientific support, and my searches and review</p> <p>21 of the clinical literature and my attendance at</p> <p>22 specialty meetings and conferences, this is not a</p> <p>23 concern, and particle loss has not been identified by</p> <p>24 any reliable scientific clinical studies as a cause of</p>

<p style="text-align: right;">Page 70</p> <p>1 a complication.</p> <p>2 Is your source for that, your review of</p> <p>3 the literature and your attendance at these scientific</p> <p>4 meetings?</p> <p>5 A And my clinical experience and the fact</p> <p>6 that these slings are supported by the American</p> <p>7 Urogynecologic Society, the Society of Gynecologic</p> <p>8 Surgeons.</p> <p>9 Q But I guess my question is, you have not</p> <p>10 performed any kind of testing on particle loss or</p> <p>11 things like that?</p> <p>12 MR. RUMANEK: I just object to the form.</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q You have not performed any testing</p> <p>15 yourself?</p> <p>16 A I have not.</p> <p>17 Q And then if we go down to the</p> <p>18 mechanically cut mesh --</p> <p>19 MR. RUMANEK: Are you on the same page?</p> <p>20 MR. THOMPSON: Yes.</p> <p>21 BY MR. THOMPSON:</p> <p>22 Q At the bottom of 16. Now we're talking</p> <p>23 about mechanically cut mesh and literature from before</p> <p>24 and after 2007 when laser-cut mesh became available do</p>	<p style="text-align: right;">Page 72</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Well, I mean difference in reaction;</p> <p>3 difference in -- I mean, have you seen anything on the</p> <p>4 other side of this issue --</p> <p>5 MR. RUMANEK: Objection to form.</p> <p>6 BY MR. THOMPSON:</p> <p>7 Q -- that would cause you to pause or cause</p> <p>8 you to rethink your opinion on this issue?</p> <p>9 A I'm sorry. Could you ask that question</p> <p>10 again?</p> <p>11 Q I guess my question is, in your</p> <p>12 literature search have you found any documents that</p> <p>13 show that there is a difference between mechanically</p> <p>14 cut and laser cut TVT material?</p> <p>15 A In terms of -- a difference in terms of</p> <p>16 what?</p> <p>17 Q A difference in terms of the properties</p> <p>18 of the mesh under tension, under insertion, in any</p> <p>19 way; any differences.</p> <p>20 A I have not seen any literature to state</p> <p>21 that, no.</p> <p>22 MR. RUMANEK: Objection to form of the</p> <p>23 question.</p> <p>24 THE WITNESS: I'm assuming that you meant</p>
<p style="text-align: right;">Page 71</p> <p>1 not demonstrate a difference in clinical effect based</p> <p>2 on whether the mesh is cut mechanically or with a</p> <p>3 laser.</p> <p>4 Do you see that?</p> <p>5 A I do.</p> <p>6 Q Now, is your basis for that, a literature</p> <p>7 review and your clinical -- the same things as</p> <p>8 earlier?</p> <p>9 A That's correct.</p> <p>10 Q You have not done any special testing on</p> <p>11 that?</p> <p>12 A That's correct.</p> <p>13 Q Have you seen any work that points to</p> <p>14 differences between the two, mechanically cut versus</p> <p>15 laser cut?</p> <p>16 A I have not.</p> <p>17 MR. RUMANEK: I just object to the form</p> <p>18 of the question.</p> <p>19 BY MR. THOMPSON:</p> <p>20 Q Well, have you seen any documents that</p> <p>21 purport to show differences between the two?</p> <p>22 MR. RUMANEK: What do you mean by</p> <p>23 differences? I mean, obviously there is a</p> <p>24 different cut.</p>	<p style="text-align: right;">Page 73</p> <p>1 scientific literature.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q Yes.</p> <p>4 MR. THOMPSON: Here we go. This is the</p> <p>5 only one I have, so let's go ahead and mark</p> <p>6 that.</p> <p>7 (Plaintiffs' Exhibit Number P-8 was</p> <p>8 marked for identification.)</p> <p>9 BY MR. THOMPSON:</p> <p>10 Q Let me identify it. This is something</p> <p>11 called a clinical expert report laser-cut mesh for</p> <p>12 Gynecare TVT, April 18th, 2006. Doctor, have you</p> <p>13 seen that before? That's an Ethicon internal</p> <p>14 document.</p> <p>15 A I don't believe so.</p> <p>16 Q Well, take a minute and have a look at</p> <p>17 it.</p> <p>18 MR. RUMANEK: Do you want her to read it?</p> <p>19 MR. THOMPSON: You know, I'm not going to</p> <p>20 ask her many questions about it, but having put</p> <p>21 it in front of her, she has a right to read it,</p> <p>22 so --</p> <p>23 MR. RUMANEK: You don't have another copy</p> <p>24 of that?</p>

<p style="text-align: right;">Page 74</p> <p>1 MR. THOMPSON: No. That is the only one</p> <p>2 I brought with me.</p> <p>3 MR. RUMANEK: Sorry. We may have a copy</p> <p>4 of it. I don't know. 7104 are the last four</p> <p>5 digits. Did you highlight this? This</p> <p>6 highlighting, is that yours?</p> <p>7 MR. THOMPSON: I don't know where that</p> <p>8 came from. That is pulled down off the machine</p> <p>9 from Crivella.</p> <p>10 THE WITNESS: Okay.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q And if you flip even further back, there</p> <p>13 are some pictures that are kind of neat.</p> <p>14 MR. RUMANEK: Let me just object to the</p> <p>15 -- before you start asking questions I'll just</p> <p>16 object to any questions asked about this</p> <p>17 document to the extent that the witness has</p> <p>18 said that she never has seen it and doesn't --</p> <p>19 there has been no foundation laid for what this</p> <p>20 is, and it appears even to be perhaps an</p> <p>21 incomplete document, unfinished, nonfinal</p> <p>22 document.</p> <p>23 THE WITNESS: Okay.</p> <p>24 BY MR. THOMPSON:</p>	<p style="text-align: right;">Page 76</p> <p>1 your opinion with regard to whether there was any</p> <p>2 difference between laser and mechanical cut?</p> <p>3 MR. RUMANEK: Objection to form to the</p> <p>4 extent --</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q TVT?</p> <p>7 MR. RUMANEK: -- she's not been offered</p> <p>8 as an expert on what Ethicon knew internally.</p> <p>9 Her opinions are not based on that.</p> <p>10 BY MR. THOMPSON:</p> <p>11 Q Well, I'm specifically going to -- you</p> <p>12 have expressed in your report an opinion that there is</p> <p>13 no difference, that it's speculative as between</p> <p>14 differences between mechanical versus laser cut, and</p> <p>15 I'm simply asking if you became aware that there were</p> <p>16 internal Ethicon documents that tested those two</p> <p>17 against each other, would you wish to incorporate</p> <p>18 those into your opinion?</p> <p>19 A Not necessarily, no, and on this page --</p> <p>20 MR. RUMANEK: I think you answered.</p> <p>21 THE WITNESS: Well, but it says there is</p> <p>22 no difference. On page 5 it says, "While the</p> <p>23 elongation properties of laser-cut mesh and</p> <p>24 mechanically cut mesh are not exactly the same,</p>
<p style="text-align: right;">Page 75</p> <p>1 Q Doctor, you've already testified that you</p> <p>2 have not seen that before, and Eric is exactly</p> <p>3 right --</p> <p>4 A Uh-huh.</p> <p>5 Q -- it's not fair to question you about</p> <p>6 the contents of it, but let me ask it this way.</p> <p>7 A Okay.</p> <p>8 MR. THOMPSON: This stack right here?</p> <p>9 MR. RUMANEK: Can I see it?</p> <p>10 MR. THOMPSON: Yeah.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q If you became aware of internal Ethicon</p> <p>13 documents that purported to test the mechanical versus</p> <p>14 the laser cut --</p> <p>15 A Yes.</p> <p>16 Q -- and that document showed various</p> <p>17 differences and various similarities --</p> <p>18 A Yes.</p> <p>19 Q -- would you wish to incorporate that</p> <p>20 into your opinion, or would you -- well, strike that.</p> <p>21 If you became aware of internal Ethicon testing</p> <p>22 between laser cut and mechanical cut and there were</p> <p>23 various tests that were run, various outcomes that</p> <p>24 were set out, would you incorporate that document into</p>	<p style="text-align: right;">Page 77</p> <p>1 they're very close and not thought to have any</p> <p>2 clinical implications."</p> <p>3 So that's mostly what I am interested in</p> <p>4 is the clinical relevance.</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q Well, now, you've now made me very happy</p> <p>7 because it sounds like you've had an opportunity to</p> <p>8 read and apprehend that document.</p> <p>9 A No. I just looked at. You just gave it</p> <p>10 to me.</p> <p>11 Q Well, no. But, I mean, you just quoted</p> <p>12 from it, so it's clear --</p> <p>13 A I've just --</p> <p>14 Q -- that you've now found some familiarity</p> <p>15 with it. Are you aware that, in fact, there were --</p> <p>16 that this document was created for the purpose of</p> <p>17 trying to ascertain whether or not they were required</p> <p>18 to get a five, 10-K approval for the laser cut versus</p> <p>19 the mechanical cut?</p> <p>20 MR. RUMANEK: Objection to the form of</p> <p>21 the question, the characterization.</p> <p>22 THE WITNESS: I've never seen this</p> <p>23 document before. I'm not sure what context it</p> <p>24 was created in, so no.</p>

<p style="text-align: right;">Page 78</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Now, the next source that I want to talk</p> <p>3 about is you have given an opinion with regard to the</p> <p>4 adequacy of the warnings and adverse events in the IFU</p> <p>5 regarding TVT --</p> <p>6 A Uh-huh.</p> <p>7 Q -- correct? Now, here is the -- this is</p> <p>8 unfortunate. I actually have the TVT form, but the</p> <p>9 TVT form that I have is reproduced as the actual size,</p> <p>10 and the one that I have that I could put in front of</p> <p>11 you is the TVT obturator, which I may not want to do</p> <p>12 that. I may want to actually use the TVT.</p> <p>13 MR. THOMPSON: All right. Here's what</p> <p>14 we're going to do. Mark this one as the next</p> <p>15 plaintiffs' exhibit.</p> <p>16 (Plaintiffs' Exhibit Number P-9 was</p> <p>17 marked for identification.)</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q I'm going to hand you Plaintiffs'</p> <p>20 Exhibit 9, and I'm actually going to fold it back to</p> <p>21 the -- because it actually has multiple languages, and</p> <p>22 you're free to look at the whole document if you want.</p> <p>23 MR. RUMANEK: Let me just say on the</p> <p>24 record just so it's clear, so what's been</p>	<p style="text-align: right;">Page 80</p> <p>1 IFU. I don't see a date.</p> <p>2 Q Now, Doctor, if I go down to the adverse</p> <p>3 reactions, do you see that?</p> <p>4 A Uh-huh. Yes, I do.</p> <p>5 Q There are four bullet points under</p> <p>6 adverse reactions. Do you see that?</p> <p>7 A Yes.</p> <p>8 Q The first one, "Punctures or lacerations</p> <p>9 of vessels, nerves, bladder, urethral bowel may occur</p> <p>10 during needle passage and may require surgical</p> <p>11 repair"; correct?</p> <p>12 A Correct.</p> <p>13 Q Now, that bullet point refers to the</p> <p>14 insertion process, does it not?</p> <p>15 A It does.</p> <p>16 Q It actually specifically refers to "may</p> <p>17 occur during needle passage"; correct?</p> <p>18 A Correct.</p> <p>19 Q Bullet point two, "Transitory local</p> <p>20 irritation at the wound site and a transitory foreign</p> <p>21 body response may occur. This response could result</p> <p>22 in extrusion, erosion, fistula formation, or</p> <p>23 inflammation."</p> <p>24 I read that correctly?</p>
<p style="text-align: right;">Page 79</p> <p>1 marked as Plaintiffs' Exhibit 9 is Bates</p> <p>2 Numbered Eth mesh 02340306, and it appears that</p> <p>3 the English version begins on page Eth mesh</p> <p>4 02340331.</p> <p>5 MR. THOMPSON: Now, having done that, I'm</p> <p>6 going to ask Eric, Eric, how about have a look</p> <p>7 at these two obturator ones, which I believe we</p> <p>8 can agree are actually identical in terms of</p> <p>9 the actual verbiage, and it might be easier on</p> <p>10 her and everybody else to use one that has a --</p> <p>11 that can be seen.</p> <p>12 MR. RUMANEK: Can you read that?</p> <p>13 THE WITNESS: I can. It's small, but --</p> <p>14 MR. RUMANEK: You can?</p> <p>15 THE WITNESS: I can.</p> <p>16 MR. RUMANEK: So she can read it. I'm</p> <p>17 happy if you want to use this. I just -- I</p> <p>18 don't want to make any representations about</p> <p>19 them being identical unless I sit here and do</p> <p>20 that comparison.</p> <p>21 BY MR. THOMPSON:</p> <p>22 Q Doctor, can you identify that as the TVT</p> <p>23 IFU that was -- I believe it's dated from 2005.</p> <p>24 A I don't see a date here. It is the TVT</p>	<p style="text-align: right;">Page 81</p> <p>1 A You did.</p> <p>2 Q Now, local irritation and transitory</p> <p>3 indicate that these conditions are going to be early</p> <p>4 and temporary? Is that not right?</p> <p>5 A Transitory? I would agree that it would</p> <p>6 at least implicate that it may -- that it should be</p> <p>7 temporary.</p> <p>8 Q The third one is, "As with all foreign</p> <p>9 bodies, Prolene may potentiate an existing infection.</p> <p>10 The plastic sheaths initially covering the Prolene</p> <p>11 mesh are designed to minimize the risk of</p> <p>12 contamination."</p> <p>13 Do you see that?</p> <p>14 A I do.</p> <p>15 Q Now, in fact, I think in your report you</p> <p>16 say you've never had a case of infection. Is that</p> <p>17 right?</p> <p>18 A That's correct.</p> <p>19 Q So this is an adverse reaction that may</p> <p>20 have been suffered by somebody else but not by you;</p> <p>21 correct?</p> <p>22 MR. RUMANEK: That may be the case for</p> <p>23 all the others as well.</p> <p>24 THE WITNESS: That's correct.</p>

<p style="text-align: right;">Page 82</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Well, if it's never been suffered by</p> <p>3 anybody, it should not be in an IFU, should it?</p> <p>4 MR. RUMANEK: Objection to form.</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q I mean, the purpose of the IFU is to</p> <p>7 apprise learned intermediaries of the adverse</p> <p>8 reactions that they may encounter?</p> <p>9 MR. RUMANEK: Objection to the form and</p> <p>10 the characterization by counsel.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q Correct?</p> <p>13 A I would say not necessarily. In a</p> <p>14 perfect world in my opinion what you are stating</p> <p>15 should be true.</p> <p>16 Q Yes.</p> <p>17 A But I think many times, in the same way</p> <p>18 that hospitals put things on their consent forms that</p> <p>19 in all likelihood would -- have never happened -- much</p> <p>20 of what goes on a consent form or an IFU is to protect</p> <p>21 oneself from the litigation, to make sure that they've</p> <p>22 sort of warned about everything that they've been told</p> <p>23 they should warn about.</p> <p>24 Q And if that's the purpose, then the --</p>	<p style="text-align: right;">Page 84</p> <p>1 MR. RUMANEK: Objection to form.</p> <p>2 THE WITNESS: That's correct.</p> <p>3 BY MR. THOMPSON:</p> <p>4 Q When would you expect to get urinary</p> <p>5 symptoms from overtensioning the tape?</p> <p>6 MR. RUMANEK: Objection to the form of</p> <p>7 the question.</p> <p>8 THE WITNESS: It's variable.</p> <p>9 BY MR. THOMPSON:</p> <p>10 Q Yes. I mean, would you expect it to take</p> <p>11 three months for it to show up?</p> <p>12 A It depends on the severity of the</p> <p>13 obstruction.</p> <p>14 Q Wouldn't, in fact, you expect the</p> <p>15 overtensioning to be immediately symptomatic?</p> <p>16 A It depends on the severity of the</p> <p>17 obstruction.</p> <p>18 Q Have you ever had a -- well, have you in</p> <p>19 your 800 TVTs, ever overtensioned a TVT?</p> <p>20 A I have.</p> <p>21 Q I'm sorry.</p> <p>22 A Yes.</p> <p>23 Q And what did you -- how did you -- I</p> <p>24 assume that you corrected it; correct?</p>
<p style="text-align: right;">Page 83</p> <p>1 A I'm not saying that's the purpose.</p> <p>2 MR. RUMANEK: Objection to the</p> <p>3 characterization.</p> <p>4 BY MR. THOMPSON:</p> <p>5 Q Well, if you're --</p> <p>6 A I'm just saying it's not necessarily true</p> <p>7 that everything that they put in the IFU has been</p> <p>8 experienced by someone. That's what I am saying.</p> <p>9 Q Well, would you think that a physician</p> <p>10 who receives the IFU could rely that all of the</p> <p>11 adverse reactions that he or she may encounter are</p> <p>12 going to be included?</p> <p>13 MR. RUMANEK: Objection to form.</p> <p>14 THE WITNESS: No.</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q The fourth one is overcorrection; i.e.,</p> <p>17 too much tension applied to the tape may cause</p> <p>18 temporary or permanent lower urinary tract</p> <p>19 obstruction. Okay?</p> <p>20 A Uh-huh, yes.</p> <p>21 Q And overcorrection, which is too much</p> <p>22 tension applied to the tape, here again, that is a</p> <p>23 problem -- the tension is applied at the time of</p> <p>24 insertion; isn't that right?</p>	<p style="text-align: right;">Page 85</p> <p>1 A Correct.</p> <p>2 Q And I assume that you viewed it as not a</p> <p>3 serious correction?</p> <p>4 A Correct.</p> <p>5 MR. RUMANEK: Objection to form.</p> <p>6 BY MR. THOMPSON:</p> <p>7 Q You did it pretty easily; is that right?</p> <p>8 A That's right.</p> <p>9 Q But if you wait ten days when this stuff</p> <p>10 starts growing back through the pores, then it becomes</p> <p>11 not so easy to do anymore; isn't that right?</p> <p>12 MR. RUMANEK: Objection to form.</p> <p>13 THE WITNESS: No.</p> <p>14 BY MR. THOMPSON:</p> <p>15 Q I'm not right?</p> <p>16 A That's not right.</p> <p>17 Q Well, when did you do the correction on</p> <p>18 the ones that you overtensioned?</p> <p>19 A I try to wait until they're at least 12</p> <p>20 weeks postop because we have data that suggests that</p> <p>21 that is the optimal time that gives you the best</p> <p>22 chance of maintaining continence and avoiding</p> <p>23 long-term irritating voiding symptoms.</p> <p>24 Q Oh, I see. So an immediate correction is</p>

<p style="text-align: right;">Page 86</p> <p>1 not supported by the data; is that right?</p> <p>2 MR. RUMANEK: Objection to form.</p> <p>3 THE WITNESS: When you say immediate, you</p> <p>4 mean within ten days?</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q Right.</p> <p>7 A Correct.</p> <p>8 Q How does it show up that it's</p> <p>9 overtension? The person can't void and they have to</p> <p>10 use the catheter? Is that how it shows up?</p> <p>11 A It varies. As I have stated in my</p> <p>12 report, it depends on a number of factors. The</p> <p>13 patient's ability to overcome the obstruction in</p> <p>14 addition to the severity of the obstruction. Some</p> <p>15 patients do present with immediate postop voiding</p> <p>16 dysfunction or retention and need to have a catheter</p> <p>17 or perform clean intermittent subcatheterization.</p> <p>18 Some patients just have recurrent urinary tract</p> <p>19 infections and a slow urinary stream. Some patients</p> <p>20 will report position changes or an interrupted stream.</p> <p>21 So the presentation varies.</p> <p>22 Q Doctor, are you aware of whether that IFU</p> <p>23 has ever been revised by Ethicon?</p> <p>24 A I believe it has.</p>	<p style="text-align: right;">Page 88</p> <p>1 time by just using the adverse reaction section</p> <p>2 of the TVT-O to ask questions about the TVT.</p> <p>3 MR. RUMANEK: And what was the question?</p> <p>4 THE WITNESS: Yeah. I don't --</p> <p>5 BY MR. THOMPSON:</p> <p>6 Q The question is, from your memory can you</p> <p>7 recall that these are substantially the same?</p> <p>8 MR. RUMANEK: Objection to form and</p> <p>9 characterization "substantially the same."</p> <p>10 THE WITNESS: I don't remember.</p> <p>11 BY MR. THOMPSON:</p> <p>12 Q Well, Doctor, if we take the 2005 TVT and</p> <p>13 we look at the 2015 revision, we note that the adverse</p> <p>14 reactions, there are substantially a higher number of</p> <p>15 adverse reactions; isn't that right?</p> <p>16 MR. RUMANEK: Objection to the use of the</p> <p>17 term "substantially higher."</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q There are 15 as opposed to four; is that</p> <p>20 right? Whoops. I think it's 14.</p> <p>21 A Yes.</p> <p>22 Q My --</p> <p>23 A There are 14 bullets.</p> <p>24 Q Fourteen instead of four. Okay. Would</p>
<p style="text-align: right;">Page 87</p> <p>1 Q And are you familiar with the revision?</p> <p>2 A I can't quote it off the top of my head,</p> <p>3 no.</p> <p>4 Q Well, that's one I do not have, so I'm</p> <p>5 going to go ahead and -- just go ahead and mark that</p> <p>6 one.</p> <p>7 (Plaintiffs' Exhibit Number P-10 was</p> <p>8 marked for identification.)</p> <p>9 MR. RUMANEK: That one.</p> <p>10 THE WITNESS: Okay.</p> <p>11 MR. RUMANEK: Do you have another copy?</p> <p>12 MR. THOMPSON: Yes. Here.</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q Doctor, this is the TVT obturator, and</p> <p>15 we're just going to have to use that. Go to page 7,</p> <p>16 and I'm going to ask you from your memory, and we</p> <p>17 probably could piece through your reliance material</p> <p>18 and find it, but I don't want to take the time to do</p> <p>19 it. From your memory can you say that the TVT-O</p> <p>20 adverse reactions is substantially the revised adverse</p> <p>21 reactions that you recall from the TVT?</p> <p>22 MR. RUMANEK: What was the question? I'm</p> <p>23 sorry.</p> <p>24 MR. THOMPSON: I'm just trying to save</p>	<p style="text-align: right;">Page 89</p> <p>1 you say that the additional adverse reactions are</p> <p>2 included because there are reports back of</p> <p>3 substantially different adverse reactions out in the</p> <p>4 community in practice?</p> <p>5 MR. RUMANEK: Objection to the form and</p> <p>6 the characterization.</p> <p>7 THE WITNESS: Let me read them quickly.</p> <p>8 MR. RUMANEK: Wait. I just want to make</p> <p>9 sure you know the question that's been asked so</p> <p>10 that you can answer the question. Could you</p> <p>11 read it back?</p> <p>12 (Thereupon, the court reporter read</p> <p>13 the pertinent portion of the record.)</p> <p>14 MR. RUMANEK: And note my objection.</p> <p>15 THE WITNESS: My answer to that would be</p> <p>16 no.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q If a physician was relying on the IFU to</p> <p>19 give him information regarding potential adverse</p> <p>20 reactions, would the earlier pre2015 adverse reactions</p> <p>21 properly give him notice of the full range of</p> <p>22 potential adverse reactions that his patient might</p> <p>23 face?</p> <p>24 MR. RUMANEK: Objection to the form of</p>

<p style="text-align: right;">Page 90</p> <p>1 the question.</p> <p>2 THE WITNESS: My answer to that is that</p> <p>3 physicians don't get their information in terms</p> <p>4 of what complications result from a procedure,</p> <p>5 from the IFU. Most of the things, from what I</p> <p>6 have read, are things that were commonly known,</p> <p>7 like acute inner chronic pain and voiding</p> <p>8 dysfunction. That's just another way of saying</p> <p>9 obstruction, which they already said in the</p> <p>10 initial IFU. So the question is, is the</p> <p>11 initial IFU sufficient? I would say yes.</p> <p>12 BY MR. THOMPSON:</p> <p>13 Q If the doctor was using the IFU</p> <p>14 information to advise or to counsel with his patient</p> <p>15 or her patient as to the risks that she might undergo</p> <p>16 with regard to this, is it your testimony that the</p> <p>17 information on adverse events included in the pre2015</p> <p>18 IFU sufficient to permit that informed discussion?</p> <p>19 MR. RUMANEK: Objection to the form of</p> <p>20 the question.</p> <p>21 THE WITNESS: Ask that question one more</p> <p>22 time.</p> <p>23 BY MR. THOMPSON:</p> <p>24 Q If the physician was going to use and</p>	<p style="text-align: right;">Page 92</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q Right.</p> <p>3 A Yes, they do.</p> <p>4 Q And the pre2015 adverse reaction does</p> <p>5 not; isn't that right?</p> <p>6 MR. RUMANEK: Objection to the form of</p> <p>7 the question; misstates her prior testimony.</p> <p>8 THE WITNESS: Transitory local irritation</p> <p>9 at the wound site is something that happens</p> <p>10 after the surgery. Infection would be</p> <p>11 something that happens after the surgery, so I</p> <p>12 would say it does.</p> <p>13 BY MR. THOMPSON:</p> <p>14 Q Now, Doctor, you've never designed any</p> <p>15 mesh products, have you?</p> <p>16 A I have not.</p> <p>17 Q Have you ever participated in any kind of</p> <p>18 focus or feedback group with regard to a mesh product?</p> <p>19 MR. RUMANEK: Objection to form.</p> <p>20 THE WITNESS: What do you mean by focus?</p> <p>21 BY MR. THOMPSON:</p> <p>22 Q If a company or an inventor is designing</p> <p>23 a product, sometimes they'll seek input from</p> <p>24 practitioners about the safety or efficacy of it.</p>
<p style="text-align: right;">Page 91</p> <p>1 incorporate the information communicated in the IFU in</p> <p>2 his discussions or her discussions with his or her</p> <p>3 patient as to the risks that the patient might</p> <p>4 undergo, is it your testimony that the pre2015 IFU</p> <p>5 sufficient?</p> <p>6 MR. RUMANEK: Objection to the form of</p> <p>7 the question.</p> <p>8 THE WITNESS: Yes. Assuming that the</p> <p>9 physician is a practicing surgeon, yes.</p> <p>10 BY MR. THOMPSON:</p> <p>11 Q Are adverse reactions included in the</p> <p>12 post -- the 2015 adverse reactions that occur and are</p> <p>13 suffered outside of the installation surgical process?</p> <p>14 MR. RUMANEK: Objection to the form of</p> <p>15 the question.</p> <p>16 THE WITNESS: You're asking, does the</p> <p>17 adverse reactions discuss things that happened</p> <p>18 after surgery?</p> <p>19 MR. RUMANEK: If you don't understand --</p> <p>20 MR. THOMPSON: Yes.</p> <p>21 MR. RUMANEK: -- it, just let him reask</p> <p>22 the question.</p> <p>23 THE WITNESS: Okay. But, yes. You're</p> <p>24 asking me, is that what is listed here?</p>	<p style="text-align: right;">Page 93</p> <p>1 Have you ever participated in that kind of process?</p> <p>2 A Yes, I have.</p> <p>3 Q And do they have to do with mesh</p> <p>4 products?</p> <p>5 A It did.</p> <p>6 Q Tell me about that.</p> <p>7 A I was asked to give my opinion about a</p> <p>8 disposable design for a mid-urethral sling by Boston</p> <p>9 Scientific.</p> <p>10 Q Yes.</p> <p>11 A I think that was two years ago, two or</p> <p>12 three years ago. To be used internationally, where</p> <p>13 they can't afford the products that we currently use.</p> <p>14 MR. RUMANEK: Let me just -- I just</p> <p>15 want -- no. I just want to make sure that</p> <p>16 there are not any sort of confidentiality</p> <p>17 issues that would preclude you from discussing</p> <p>18 that. I'm not saying that there are. I just</p> <p>19 want to make sure.</p> <p>20 MR. THOMPSON: Well, let's do this: How</p> <p>21 about, Mr. Court Reporter, can you mark that</p> <p>22 section, and we'll make sure that is -- I guess</p> <p>23 the whole thing will be labeled confidential.</p> <p>24 MR. RUMANEK: Well, and I'm not saying we</p>

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<p>1 need to. I just don't want her to say -- and</p> <p>2 just respond to your question, to violate any</p> <p>3 sort of -- I don't know whether --</p> <p>4 THE WITNESS: Maybe I could --</p> <p>5 MR. RUMANEK: -- there is or is not.</p> <p>6 THE WITNESS: -- cross the Boston</p> <p>7 Scientific part.</p> <p>8 BY MR. THOMPSON:</p> <p>9 Q Well, let me tell you this: I would not</p> <p>10 rely on Boston Scientific to be friendly about</p> <p>11 anything. Okay? So I think Eric's advice is probably</p> <p>12 good. I will not inquire any further about that.</p> <p>13 All right. And of course you're not a chemist?</p> <p>14 MR. RUMANEK: Objection to form.</p> <p>15 THE WITNESS: I'm not.</p> <p>16 BY MR. THOMPSON:</p> <p>17 Q Doctor, in your report you relate that</p> <p>18 you're being paid by the hour to be an expert in these</p> <p>19 matters; is that right?</p> <p>20 A That's correct.</p> <p>21 Q Do you have with you some sort of a</p> <p>22 summary or invoice showing the amount of time that you</p> <p>23 have spent on a -- I am particularly interested in the</p> <p>24 Bailey case, but I know that the later cases today are</p>	<p>1 April --</p> <p>2 A Yes.</p> <p>3 Q -- correct?</p> <p>4 A That's correct.</p> <p>5 Q Now, you've actually given some</p> <p>6 deposition testimony, and I think you even gave court</p> <p>7 testimony in Philadelphia; is that right?</p> <p>8 A Video deposition.</p> <p>9 Q In that video deposition what -- was that</p> <p>10 part of a lawsuit that was -- has it been tried, or do</p> <p>11 you know?</p> <p>12 A It was, I believe, yes.</p> <p>13 Q But you didn't appear in Philadelphia?</p> <p>14 You appeared by video deposition?</p> <p>15 A I did appear in Philadelphia, but it was</p> <p>16 by video. I didn't testify in court.</p> <p>17 Q You didn't physically go to the</p> <p>18 Philadelphia county courthouse and testify in person?</p> <p>19 A That's correct.</p> <p>20 Q Is that type of activity included in</p> <p>21 this?</p> <p>22 MR. RUMANEK: Let's go back off the</p> <p>23 record just a second.</p> <p>24 MR. THOMPSON: Yes.</p>
Page 95	Page 97
<p>1 also going to be interested in that as well. Do you</p> <p>2 have that?</p> <p>3 MR. RUMANEK: I have that.</p> <p>4 MR. THOMPSON: There is a little bit of</p> <p>5 Kabuki theater going on here. Eric and I</p> <p>6 already talked about this earlier.</p> <p>7 MR. RUMANEK: And let's go off the record</p> <p>8 just for a second.</p> <p>9 (Discussion ensued off the record.)</p> <p>10 THE REPORTER: Are we back on the record?</p> <p>11 MR. THOMPSON: Please.</p> <p>12 (Plaintiffs' Exhibit Number P-11 was</p> <p>13 marked for identification.)</p> <p>14 MR. RUMANEK: And, Fred, the only thing I</p> <p>15 want to note on the record, I think you asked</p> <p>16 her if she is being paid hourly. Her report</p> <p>17 notes that she is being paid hourly, but for</p> <p>18 depositions she has a fee per day, so I just --</p> <p>19 it is a very minor point, but I just wanted to</p> <p>20 make sure that was clear on the record.</p> <p>21 MR. THOMPSON: All right.</p> <p>22 BY MR. THOMPSON:</p> <p>23 Q Doctor, handing you this prepared</p> <p>24 document, I noticed that the first entry is in</p>	<p>1 (Discussion ensued off the record.)</p> <p>2 THE REPORTER: Back on?</p> <p>3 MR. THOMPSON: Yes, please.</p> <p>4 BY MR. THOMPSON:</p> <p>5 Q Doctor, this prepared document is an</p> <p>6 invoice that shows your activity in reviewing and</p> <p>7 preparing the reports for wave two in Ethicon; is that</p> <p>8 right?</p> <p>9 A That's correct.</p> <p>10 MR. RUMANEK: Up through --</p> <p>11 MR. THOMPSON: There is --</p> <p>12 MR. RUMANEK: -- May 31.</p> <p>13 MR. THOMPSON: Up through May 31.</p> <p>14 BY MR. THOMPSON:</p> <p>15 Q And so you have additional time that you</p> <p>16 will invoice, and you hope that Ethicon is good for</p> <p>17 it?</p> <p>18 A That Troutman & Sanders is, yes.</p> <p>19 Q Oh, okay. They're good for it, but you</p> <p>20 hope that they get reimbursed by J & J?</p> <p>21 MR. RUMANEK: Objection to form.</p> <p>22 BY MR. THOMPSON:</p> <p>23 Q See if I can make him object to that.</p> <p>24 Okay.</p>

<p style="text-align: right;">Page 98</p> <p>1 (Discussion ensued off the record.)</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q But you have given other -- you've given</p> <p>4 a video testimony in Philadelphia? You've given other</p> <p>5 depositions before today; is that correct?</p> <p>6 A That's correct.</p> <p>7 Q In other cases? In other Ethicon TVT</p> <p>8 cases or Ethicon -- strike all that. In other Ethicon</p> <p>9 cases; correct?</p> <p>10 A That's correct.</p> <p>11 Q And you have actually been retained and</p> <p>12 have provided expert reports on Prolift devices as</p> <p>13 well; is that correct?</p> <p>14 A That's correct.</p> <p>15 Q And in each of those instances where you</p> <p>16 either gave a report and signed it or you gave</p> <p>17 deposition testimony or where you gave courtroom</p> <p>18 testimony by videotape, you understand that in each of</p> <p>19 those instances you had an obligation to be of candor</p> <p>20 and truth telling?</p> <p>21 MR. RUMANNEK: Objection to form.</p> <p>22 BY MR. THOMPSON:</p> <p>23 Q Do you understand that?</p> <p>24 MR. RUMANNEK: Objection to form.</p>	<p style="text-align: right;">Page 100</p> <p>1 reference to the earlier, I think 2014 AUGS statement.</p> <p>2 Let's see if I can get it here. Here we go.</p> <p>3 MR. THOMPSON: Let me mark that.</p> <p>4 (Plaintiffs' Exhibit Number P-12 was</p> <p>5 marked for identification.)</p> <p>6 BY MR. THOMPSON:</p> <p>7 Q I'm going to hand that to you.</p> <p>8 A Uh-huh.</p> <p>9 Q That's a statement that you made</p> <p>10 reference to several times in your report; is that</p> <p>11 correct?</p> <p>12 A That's correct.</p> <p>13 Q Now, Doctor, is there any effort in that</p> <p>14 report to include a fair and balanced bibliography</p> <p>15 that shows articles and information that show problems</p> <p>16 with the procedures?</p> <p>17 MR. RUMANNEK: Objection to form. What do</p> <p>18 you mean by -- I just want to make sure of the</p> <p>19 question. What do you mean by shows problems?</p> <p>20 BY MR. THOMPSON:</p> <p>21 Q That indicate that the polypropylene</p> <p>22 devices are not safer or more efficacious than a</p> <p>23 native tissue repair or that there are rates of</p> <p>24 erosion or other complications that require further</p>
<p style="text-align: right;">Page 99</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q And so is there anything that, on</p> <p>4 reflection, since you've given those reports or those</p> <p>5 depositions or that courtroom testimony, that you have</p> <p>6 realized that you have a different opinion or a</p> <p>7 different statement, or do you stand by all of your</p> <p>8 testimony?</p> <p>9 MR. RUMANNEK: Hold on just a second. I'm</p> <p>10 going to object to the form to the extent</p> <p>11 you're asking her whether she stands by</p> <p>12 testimony that occurred months and maybe even a</p> <p>13 year ago. If you want to show her that</p> <p>14 testimony and have her reread it --</p> <p>15 MR. THOMPSON: Well, I don't -- I'm</p> <p>16 satisfied that the answer to this is going to</p> <p>17 be yes. I don't have any great smoking gun.</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q I just want to make sure that the whole</p> <p>20 body of your testimony is available as we go forward,</p> <p>21 that there is nothing that you repudiate.</p> <p>22 A That's correct.</p> <p>23 Q Doctor, let me ask you about the AUGS</p> <p>24 statement, and this one is a new one, but you make</p>	<p style="text-align: right;">Page 101</p> <p>1 attention.</p> <p>2 MR. RUMANNEK: Objection to the form of</p> <p>3 the question. Misstates the statement.</p> <p>4 THE WITNESS: This is a position</p> <p>5 statement on mesh mid-urethral slings and the</p> <p>6 treatment of stress incontinence. It's not a</p> <p>7 paper about complications.</p> <p>8 BY MR. THOMPSON:</p> <p>9 Q Yes.</p> <p>10 A So no, they don't talk about any data</p> <p>11 that -- that references complications other than the</p> <p>12 fact that mid-urethral slings are safe and</p> <p>13 efficacious, and they do reference data to support</p> <p>14 their statements.</p> <p>15 Q And is there anything within the body of</p> <p>16 that statement that talks about risks and</p> <p>17 complications and adverse events that have been</p> <p>18 suffered by patients?</p> <p>19 A Let me read it.</p> <p>20 MR. RUMANNEK: Yeah. Read the statement,</p> <p>21 yes.</p> <p>22 THE WITNESS: Okay. Could you ask the</p> <p>23 question again?</p> <p>24 BY MR. THOMPSON:</p>

<p style="text-align: right;">Page 102</p> <p>1 Q I guess the question is, is there any</p> <p>2 discussion there about risks, adverse events, and</p> <p>3 complications that are suffered by patients and means</p> <p>4 and modalities of caring for them?</p> <p>5 A The paper doesn't go into detail about</p> <p>6 specific complications, but it says that the</p> <p>7 mid-urethral sling is associated with less pain,</p> <p>8 shorter hospitalization, faster return to usual</p> <p>9 activities, and reduced cost. So they talk about the</p> <p>10 fact that there are, you know, things that you have to</p> <p>11 consider in terms of pain and that kind of thing, but</p> <p>12 it's less with the mid-urethral sling than it is with</p> <p>13 traditional repairs, and they reference a paper. They</p> <p>14 reference citation Number 13.</p> <p>15 Q So the passage you just read, is it wrong</p> <p>16 for me to characterize that as an advocacy position?</p> <p>17 MR. RUMANEK: Objection to form.</p> <p>18 THE WITNESS: No. I don't think that's</p> <p>19 wrong.</p> <p>20 BY MR. THOMPSON:</p> <p>21 Q In fact, that position statement is</p> <p>22 advocating TVTs or mid -- I shouldn't say TVTs;</p> <p>23 mid-urethral slings -- as a means for treating stress</p> <p>24 incontinence?</p>	<p style="text-align: right;">Page 104</p> <p>1 same thing. The Society of Gynecologic</p> <p>2 Surgeons does the same thing. The American</p> <p>3 Urologic Association does the same thing.</p> <p>4 So their job is to support physicians and</p> <p>5 research in the communities that they serve but</p> <p>6 also to educate about what they think are best</p> <p>7 practices. It's the surgeon's job to educate</p> <p>8 patients about what they think is the best</p> <p>9 option for that individual patient.</p> <p>10 BY MR. THOMPSON:</p> <p>11 Q Is it any part of the AUGS to make their</p> <p>12 surgeons, their members aware that poorly performing</p> <p>13 implanters are causing complications for their</p> <p>14 patients?</p> <p>15 MR. RUMANEK: Objection to the form of</p> <p>16 the question to the extent that now you're</p> <p>17 asking her to testify about what AUGS should</p> <p>18 do.</p> <p>19 THE WITNESS: Could you repeat the</p> <p>20 question?</p> <p>21 BY MR. THOMPSON:</p> <p>22 Q I'm fascinated by the fact that nobody</p> <p>23 owns up to the fact that in the hands of a competent</p> <p>24 and well-trained surgeon, that the complication rate</p>
<p style="text-align: right;">Page 103</p> <p>1 A Absolutely.</p> <p>2 Q If the AUGS is not the body that sets out</p> <p>3 objectively risks, complications, and other factors to</p> <p>4 be considered by patients in deciding whether or not</p> <p>5 to have a mesh surgery, who is?</p> <p>6 MR. RUMANEK: Objection to form.</p> <p>7 THE WITNESS: Could you ask that question</p> <p>8 again?</p> <p>9 BY MR. THOMPSON:</p> <p>10 Q If the AUGS is not the group that sets</p> <p>11 out the risks and benefits, complication potential to</p> <p>12 assist patients in making an informed decision as to</p> <p>13 whether or not to have the surgery, then who is?</p> <p>14 MR. RUMANEK: Objection to form.</p> <p>15 THE WITNESS: The American Urogynecologic</p> <p>16 Society makes position statements, practice</p> <p>17 bulletins, different peer articles -- peer --</p> <p>18 what is the right word? Different -- they put</p> <p>19 together different statements and practice</p> <p>20 bulletins to educate surgeons about what they</p> <p>21 think is the best clinical practice. That is</p> <p>22 based on scientific evidence, and that's true</p> <p>23 for all medical societies. The American</p> <p>24 College of Obstetrics and Gynecology does the</p>	<p style="text-align: right;">Page 105</p> <p>1 for this device seems low or, in your case, zero.</p> <p>2 Whereas --</p> <p>3 A Well --</p> <p>4 Q -- in other people --</p> <p>5 A -- that's not exactly true.</p> <p>6 Q Well, in other people it's 20, 30</p> <p>7 percent. There are surgeons out there who are doing</p> <p>8 terrible things, and yet I don't see a single</p> <p>9 organization that speaks up for that and says, we've</p> <p>10 got to do something about that. It's like giving a</p> <p>11 formula one car to a 15-year-old. I mean, there is a</p> <p>12 problem, and I don't see anybody stepping up to it.</p> <p>13 That's my question.</p> <p>14 MR. RUMANEK: I'll object. That's a</p> <p>15 narrative, not a question, and I have no clue</p> <p>16 what the question is.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q The question is, who does that?</p> <p>19 MR. RUMANEK: Objection.</p> <p>20 THE WITNESS: So -- first of all, you're</p> <p>21 overstating the risks, so if we talk about a</p> <p>22 case like Bailey, for instance, where that</p> <p>23 physician had a higher voiding dysfunction rate</p> <p>24 than average, than what's quoted</p>

<p style="text-align: right;">Page 106</p> <p>1 internationally in the literature, please 2 understand that that rate is still equivalent 3 to the Burch; right? So she's still getting a 4 very successful procedure with a voiding 5 dysfunction rate that's actually still even 6 lower than the Burch. I mean, the voiding 7 dysfunction with the Burch can be up to 8 34 percent. 9 So if you are saying that we should make 10 sure that every surgeon is perfect before we 11 allow them to do mid-urethral slings, that's 12 not realistic, but even in the most imperfect 13 hands usually the success rate and risks of 14 complications is less than what we were doing 15 before the sling was invented, so that's part 16 of it. 17 The second thing is, we do acknowledge 18 and have been studying the fact that surgeon 19 volume is related to patient outcomes, and, in 20 fact, in a recent paper by -- I think the 21 author's last name is Welk out of Canada, it 22 was a great paper that illustrated that 23 high-volume surgeons, those that are in the 24 75th percentile, have less complication rates</p>	<p style="text-align: right;">Page 108</p> <p>1 for stress incontinence. Again, 20 percent is 2 acceptable. Is it optimal? Maybe not, but it's 3 acceptable. 4 MR. THOMPSON: Doctor, as you can tell, 5 I'm endlessly fascinated by that subject, but I 6 would like to, if we could, maybe move on to 7 Miss Bailey and do that before lunch. Is that 8 a -- I mean, you surgeons have been up since 9 5 a.m., so this may well be a very important 10 lunchtime, but I would almost like to, if we 11 could press through, that would be great. I 12 don't intend to take that huge amount of time. 13 MR. RUMANEK: So the only question I 14 would have for Dr. Lowman is, does she want to 15 take a couple of minutes to regroup, to reread 16 the Bailey reports since we've been talking 17 about the TVT, if that's needed, or we can just 18 transition right on to -- 19 MR. THOMPSON: Actually, what that does 20 that allows me -- I'd asked my lady over the 21 telephone -- 22 MR. RUMANEK: Yes. 23 MR. THOMPSON: It gives me some 24 opportunity for her before I close the record,</p>
<p style="text-align: right;">Page 107</p> <p>1 than those are in the less than the 75th 2 percentile. 3 It is unreasonable, however, to assume -- 4 to try to create conditions where every surgeon 5 is going to do 400 TVTs a year. It's just not 6 possible. So our best option is to go with the 7 best option, and that's the mid-urethral sling. 8 BY MR. THOMPSON: 9 Q Your answer makes sense only in a world 10 where it's important to keep the poorest-performing 11 surgeons well compensated; isn't that right? 12 MR. RUMANEK: Objection to the form of 13 the question. 14 THE WITNESS: No. 15 BY MR. THOMPSON: 16 Q If Kaiser Permanente had a surgeon who 17 had a complication rate like Dr. Perlow, what would 18 you do -- 19 MR. RUMANEK: Objection to form. 20 BY MR. THOMPSON: 21 Q -- as the medical director? 22 A To have someone who has voiding 23 dysfunction after mid-urethral sling is a known 24 potential complication after any suspension procedure</p>	<p style="text-align: right;">Page 109</p> <p>1 to ask a question if she thinks that I need to 2 ask it. 3 MR. RUMANEK: And I need to look back at 4 my notes to see if I have anything that I want 5 to follow up on, so why don't we take a little 6 break? 7 MR. THOMPSON: Yes. That would be great. 8 Thank you. 9 MR. RUMANEK: Paige, are you going to 10 have anything? 11 THE REPORTER: Are we off the record? 12 MR. RUMANEK: Yes. 13 (A recess was taken.) 14 THE REPORTER: Mr. Thompson? I have that 15 they want this transcribed within three days. 16 Do you know if that's what you-all wanted was 17 three-day delivery? 18 MR. THOMPSON: Yes. That would be great. 19 THE REPORTER: So by Wednesday or so, and 20 I believe that as part and parcel of the 21 realtime, we send you a rough draft the next 22 day or so? 23 MR. THOMPSON: Yes. That would be great. 24 /</p>

<p style="text-align: right;">Page 110</p> <p>1 EXAMINATION</p> <p>2 BY MR. RUMANEK:</p> <p>3 Q Dr. Lowman, I have just a few questions</p> <p>4 for you. You testified earlier about your decision to</p> <p>5 use the TVT over the TVT-O. Do you recall that</p> <p>6 testimony?</p> <p>7 A I do.</p> <p>8 Q Do you have an opinion as to whether the</p> <p>9 complication rates for the TVT-O are acceptably low?</p> <p>10 A They are.</p> <p>11 Q Based on your experience and review of</p> <p>12 the medical literature, is it your opinion that the</p> <p>13 TVT-O is safe and effective for treatment of stress</p> <p>14 urinary incontinence?</p> <p>15 A It is.</p> <p>16 Q Is that opinion shared -- is that opinion</p> <p>17 reflected in the AUGS/SUFU statement that was marked</p> <p>18 as Plaintiffs' Exhibit 12 as well?</p> <p>19 A Yes, it is.</p> <p>20 Q And --</p> <p>21 A It is.</p> <p>22 Q And do you have any reason to disagree</p> <p>23 with the position statement from AUGS and SUFU as it</p> <p>24 relates to use of transobturator slings?</p>	<p style="text-align: right;">Page 112</p> <p>1 terms of women's health, is supporting this statement</p> <p>2 that was initially drafted by AUGS and SUFU.</p> <p>3 MR. RUMANEK: That's all the questions I</p> <p>4 have.</p> <p>5 FURTHER EXAMINATION</p> <p>6 BY MR. THOMPSON:</p> <p>7 Q Doctor, let me see your little</p> <p>8 handwritten notes here. These are your handwriting?</p> <p>9 A Yes, it is. Can't read it, can you?</p> <p>10 Q Well, I'm fascinated. Did you write this</p> <p>11 as we went --</p> <p>12 A No.</p> <p>13 Q -- today, or you brought these in with</p> <p>14 you --</p> <p>15 A I brought them --</p> <p>16 Q -- as sort of a reference?</p> <p>17 A Uh-huh. I knew I wasn't going to be able</p> <p>18 to remember every society that's supporting that</p> <p>19 position statement.</p> <p>20 MR. THOMPSON: Well, let's go ahead. We</p> <p>21 can mark these. If you mark that as a single</p> <p>22 exhibit, it is fine with me.</p> <p>23 (Plaintiffs' Exhibit Number P-13 was</p> <p>24 marked for identification.)</p>
<p style="text-align: right;">Page 111</p> <p>1 A I don't.</p> <p>2 Q In response to questions by Mr. Thompson,</p> <p>3 he asked you whether you believe the AUGS/SUFU</p> <p>4 statement was advocacy. Do you recall that question?</p> <p>5 A I do.</p> <p>6 Q What did you mean when you referred to</p> <p>7 you -- you agreed that it was advocacy?</p> <p>8 A What I am stating is that the American</p> <p>9 Urogynecologic Society and the Society of Urodynamics</p> <p>10 in Female Pelvic Medicine and Urogenital</p> <p>11 Reconstruction are compiling a statement in support of</p> <p>12 the use of the mid-urethral sling in treating stress</p> <p>13 urinary incontinence.</p> <p>14 So if you characterize that as advocacy,</p> <p>15 I would agree that that's what that is, but it's based</p> <p>16 on the scientific evidence, the totality of the</p> <p>17 scientific evidence, and furthermore, it's not just</p> <p>18 AUGS and SUFU; it's now the American Association of</p> <p>19 Gynecologic Laparoscopists, the American Urologic</p> <p>20 Association, the Society of Gynecologic Surgeons, the</p> <p>21 National Association for Continence, the -- what was</p> <p>22 the other one? Women's Health Foundation.</p> <p>23 So basically every organization in this</p> <p>24 country that has any skin in the game, if you will, in</p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. THOMPSON:</p> <p>2 Q A couple of questions. With regard to</p> <p>3 patients, Doctor, do you believe that a patient must</p> <p>4 give informed consent before a surgical procedure is</p> <p>5 performed on them?</p> <p>6 MR. RUMANEK: Objection to form of the</p> <p>7 question.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. THOMPSON:</p> <p>10 Q Do you believe that informed consent</p> <p>11 contains a complete description of the benefits and</p> <p>12 the risks that are entailed by that surgery?</p> <p>13 MR. RUMANEK: Objection to form.</p> <p>14 THE WITNESS: I think informed consent</p> <p>15 should contain information that's clinically</p> <p>16 relevant and helpful in helping the patient</p> <p>17 make a decision that's reasonable.</p> <p>18 BY MR. THOMPSON:</p> <p>19 Q And that includes a discussion of risks</p> <p>20 and potential complications; isn't that right?</p> <p>21 MR. RUMANEK: Objection to form.</p> <p>22 THE WITNESS: That's correct.</p> <p>23 BY MR. THOMPSON:</p> <p>24 Q Doctor, prior to the 2015 -- well, 2014</p>

<p style="text-align: right;">Page 114</p> <p>1 revision of the TVT and TVT-O IFU, do you believe that</p> <p>2 a patient would have received sufficient information</p> <p>3 regarding the implanting of the TVT in order to make</p> <p>4 an informed decision as to whether or not to have that</p> <p>5 implant?</p> <p>6 MR. RUMANEK: Objection to the form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. THOMPSON:</p> <p>9 Q Does a discussion between the doctor and</p> <p>10 a patient with regard to risk and benefits of a</p> <p>11 surgery, include a discussion as to rates of</p> <p>12 complication?</p> <p>13 MR. RUMANEK: Objection to the form.</p> <p>14 THE WITNESS: Not always.</p> <p>15 BY MR. THOMPSON:</p> <p>16 Q Does a discussion between a doctor and</p> <p>17 patient as to the risk and benefits of a procedure,</p> <p>18 include a discussion as to the severity of</p> <p>19 complications?</p> <p>20 MR. RUMANEK: Objection to form.</p> <p>21 THE WITNESS: Not always.</p> <p>22 BY MR. THOMPSON:</p> <p>23 Q Does the discussion between doctor and</p> <p>24 patient include a discussion as to the difficulty of</p>	<p style="text-align: right;">Page 116</p> <p>1 thing. We can go off the record.</p> <p>2 (Discussion ensued off the record.)</p> <p>3 THE REPORTER: Mr. Rumanek? They want</p> <p>4 this on a three-day delivery, by Wednesday, the</p> <p>5 final transcript. Is that what you-all wanted,</p> <p>6 or did you want regular, or what --</p> <p>7 MR. RUMANEK: Yeah, that's fine.</p> <p>8 THE REPORTER: Three day.</p> <p>9 MR. RUMANEK: I need a rough.</p> <p>10 (Deposition concluded at 12:09 p.m.)</p> <p>11 (Pursuant to Rule 30(e) of the Federal</p> <p>12 Rules of Civil Procedure, signature of the witness has</p> <p>13 been reserved.)</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 115</p> <p>1 repair or difficulty of treating a complication?</p> <p>2 MR. RUMANEK: Objection to form.</p> <p>3 THE WITNESS: Not always.</p> <p>4 BY MR. THOMPSON:</p> <p>5 Q If I relate the questions, the three</p> <p>6 previous questions, specifically to the implantation</p> <p>7 of a TVT or TVT-O device, would you believe that that</p> <p>8 discussion should include the rate of complication</p> <p>9 with regard to a TVT, TVT-O?</p> <p>10 MR. RUMANEK: Objection to form.</p> <p>11 THE WITNESS: That would be optimal, yes.</p> <p>12 BY MR. THOMPSON:</p> <p>13 Q And how about the severity of potential</p> <p>14 complications?</p> <p>15 MR. RUMANEK: Objection to form.</p> <p>16 THE WITNESS: That would be optimal also.</p> <p>17 BY MR. THOMPSON:</p> <p>18 Q And the difficulty in correcting a</p> <p>19 complication?</p> <p>20 MR. RUMANEK: Objection to form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 MR. THOMPSON: That's all the questions I</p> <p>23 have on that. Let's move on to Miss Bailey.</p> <p>24 MR. RUMANEK: Fred, let me just say one</p>	<p style="text-align: right;">Page 117</p> <p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 STATE OF GEORGIA)</p> <p>4 COUNTY OF GWINNETT)</p> <p>5</p> <p>6 I hereby certify that the foregoing</p> <p>7 transcript was taken down, as stated in the</p> <p>8 caption, and the proceedings were reduced to</p> <p>9 typewriting under my direction and control.</p> <p>10 I further certify that the transcript</p> <p>11 is a true and correct record of the evidence</p> <p>12 given at the said proceedings.</p> <p>13 I further certify that I am neither a</p> <p>14 relative or employee or attorney or counsel to</p> <p>15 any of the parties, nor financially or</p> <p>16 otherwise interested in this matter.</p> <p>17 This the 28th day of June,</p> <p>18 2016.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p style="text-align: center;">_____ THOMAS R. BREZINA, B-2035</p>

Joye Lowman, M.D.

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2 **ACKNOWLEDGMENT OF DEPONENT**

3

4 I, _____, do

5 hereby certify that I have read the

6 foregoing pages, and that the same is

7 a correct transcription of the answers

8 given by me to the questions therein

9 propounded, except for the corrections or

10 changes in form or substance, if any,

11 noted in the attached Errata Sheet.

12

13

14 _____

15 **JOYE LOWMAN, M.D. DATE**

16

17

18 Subscribed and sworn

19 to before me this

20 _____ day of _____, 20____.

21 My commission expires: _____

22 _____

23 Notary Public

24

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1 **LAWYER'S NOTES**

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